About Grünenthal

The Grünenthal Group is an independent, family-owned, international research-based pharmaceutical company headquartered in Aachen, Germany. The parent company of the Grünenthal Group is Grünenthal Pharma GmbH Co. & KG.

We are an entrepreneurial specialist delivering true benefits to patients. By sustainably investing in research and development above the industrial average, we are committing to innovation in order to treat unmet medical needs and bring value-adding products to markets.

Grünenthal is a fully integrated research and development company with a long track record of bringing innovative pain treatments and state-of-the-art technologies to patients. Altogether, the Grünenthal Group is present in 32 countries with affiliates in Europe, Latin America, and the US. Grünenthal products are sold in more than 155 countries, and approximately 5,300 employees work for the Grünenthal Group worldwide. In 2015, Grünenthal achieved revenues of €1.2 billion. In 2015, no significant changes in the Group structure took place.

Market presence

Facts & Figures

<table>
<thead>
<tr>
<th>Corporate figures in € million</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenues</td>
<td>1,212</td>
</tr>
<tr>
<td>Revenue growth vs. previous year</td>
<td>+ 5%</td>
</tr>
<tr>
<td>R&amp;D costs</td>
<td>233</td>
</tr>
<tr>
<td>R&amp;D costs ratio (R&amp;D costs/revenues)</td>
<td>19%</td>
</tr>
<tr>
<td>Income before taxes (IBT)</td>
<td>116</td>
</tr>
<tr>
<td>Sustainable IBT</td>
<td>87</td>
</tr>
<tr>
<td>Income after taxes</td>
<td>83</td>
</tr>
<tr>
<td>Equity ratio (%)</td>
<td>61%</td>
</tr>
</tbody>
</table>
Facts and Figures

Net revenues split by business unit (BU)/strategic business unit (SBU)

- BU North America: 9%
- SBU Europe: 58%
- SBU Latin America: 26%
- Others: 7%

€ 1,212 mn

Percentage distribution of revenues 2015 in Europe and Latin America

Europe: strong coverage of the home market

Revenues 2015: € 703 million with a focused portfolio in a stable macro economy and a culture where WHO step II and III analgesics are fully accepted (also outside cancer pain)

- Pain: 90%
- Others: 10%

Latin America: out-of-pocket driven markets balance payer-driven markets in EU

Revenues 2015: € 322 million with a broader portfolio in a sometimes uncertain but dynamic market environment where strong opioids are very restricted

- Pain: 36%
- Others: 34%
- Women’s health: 14%
- CNS: 10%
- Urology: 1%
- Antimicrobial: 5%
Facts and Figures

Employees group-wide

<table>
<thead>
<tr>
<th></th>
<th>Women</th>
<th>Men</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employees group wide</td>
<td>2,787</td>
<td>2,477</td>
<td>5,264</td>
</tr>
<tr>
<td>Europe</td>
<td>1,593</td>
<td>1,329</td>
<td>2,922</td>
</tr>
<tr>
<td>LatAm</td>
<td>1,165</td>
<td>1,115</td>
<td>2,280</td>
</tr>
<tr>
<td>US</td>
<td>29</td>
<td>33</td>
<td>62</td>
</tr>
</tbody>
</table>

Grüntenthal’s business is not subject to seasonal variations; there is no seasonal variation in employment numbers. Employee wages and benefits group-wide: € 359.4 million.

Group-wide absenteeism rate: 3.85%

Thereof:
- 3.75% illness-related and non-workplace accident absences
- 0.10% related to occupational accidents.

Accidents:
- In total: 46 occupational accidents, equivalent to 1,405 lost working days.
  - 25 accidents occurred in the affiliates
  - 22 accidents occurred on production sites and provoked 350 lost working days (2,803 lost working hours)
- No serious or fatal accidents, no case of occupational disease

Lost Time Injury Frequency

The Lost Time Injury Frequency (LTIF) at the production sites was reduced from 16.8 in 2008 to 4.6 in 2015.

Working Time Lost Due To Working Accidents

The Working Time Lost Due To Working Accidents (WTLWA) at the production sites was reduced from 1,231 in 2011 to 477 in 2015.

Energy and water consumption of the production sites

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy Consumption (Electricity, Oil &amp; Gas) [kWh]</td>
<td>99,228,886</td>
</tr>
<tr>
<td>Electricity Consumption [kWh]</td>
<td>42,797,178</td>
</tr>
<tr>
<td>Oil Consumption [kWh]</td>
<td>977,614</td>
</tr>
<tr>
<td>Gas Consumption [kWh]</td>
<td>55,454,094</td>
</tr>
<tr>
<td>Tap water from municipal water supplies [m³]</td>
<td>192,432</td>
</tr>
<tr>
<td>Tap water from own source [m³]</td>
<td>87,663</td>
</tr>
<tr>
<td>Cooling water from own groundwater source [m³]</td>
<td>904,527</td>
</tr>
</tbody>
</table>

Waste and CO₂ emission of production sites

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO₂ emission (Electricity, Oil &amp; Gas) [to CO₂e]</td>
<td>26,211</td>
</tr>
<tr>
<td>CO₂ emission electricity [to CO₂e]</td>
<td>13,040</td>
</tr>
<tr>
<td>CO₂ emission oil [to CO₂e] (0.2653 kg CO₂/kWh)</td>
<td>259</td>
</tr>
<tr>
<td>CO₂ emission gaz [to CO₂e] (0.203 kg CO₂/kWh)</td>
<td>12,912</td>
</tr>
<tr>
<td>Hazardous waste (liquid and solid) [to]</td>
<td>3,230</td>
</tr>
<tr>
<td>Non-hazardous waste (liquid and solid) [to]</td>
<td>2,641</td>
</tr>
<tr>
<td>Total waste [to]</td>
<td>5,871</td>
</tr>
</tbody>
</table>

1 The five production sites cover 59.3 % (3,122 FTEs) of all employees of Grüntenthal.
2 The Lost Time Injury Frequency (LTIF) and Working Time Lost Due To Working Accidents (WTLWA) are recorded in a standardized manner. These rates are calculated as the number of accidents or the number of lost working hours per one million hours worked.
Editorial

Dear Readers,

Sustainability is a key focus of Grünenthal. By sustainably investing in research and development above the industrial average, we are committing to innovation in order to treat patients with unmet medical needs and bring value-adding products to markets.

Grünenthal is a fully integrated research and development company with a long track record of bringing innovative pain treatments and state-of-the-art technologies to patients. This is reflected in our purpose: we are an entrepreneurial specialist delivering true benefits to patients.

As an independent, family-owned, international research-based pharmaceutical company we focus on long-term actions. Sustainability has been anchored in our strategy and our daily work for many years. We identify business opportunities to ensure we are sustainable in the long-term.

Our common goal is to become the leading address and a model company among the mid-caps of the pharmaceutical industry. In order to make a real difference in the lives of our patients and to improve their quality of life, we focus on products and solutions that go beyond the current standard of care. Innovation continues to be the core of our business, and to improve the situation of patients in need is the motivation for everyone at Grünenthal, every day. Innovative solutions are the only sustainable way to win, even in times of increasing hurdles to market access.

To also be successful in the future, we have to anticipate and address the fast change and increasing complexity of the environment: we need to be ahead of the scientific trends that are the basis for and shape future innovation. In addition, the increasing pressure on healthcare costs drives the trend toward a performance-related payment and/or reimbursement (pay for performance). Due to this and other factors, the market access conditions are getting more and more complex. As a result, the future market access environment in Europe, but also in Latin America and the United States, will be an important success factor and requires a diversified R&D portfolio.

Pain was, is, and will be our core expertise. Worldwide, 1.5 billion people suffer from chronic pain. One in five patients has lost their work due to the pain. In the European Union alone, every year 100 million patients are diagnosed with chronic pain, and 500 million working days are lost due to this condition – an economic damage of € 34 billion.

As an expert for pain treatment, we care about patients suffering from pain around the globe. In Europe, 15% of patients who suffer from chronic pain are treated with a product from our own R&D departments. Therewith, we sustainably contribute to society by improving the quality of life for patients – in Europe, Latin America, and around the globe.

To ensure we are sustainable in the long-term, we will also go beyond pain and expand to new therapeutic areas, such as in selected inflammatory diseases, Duchenne Muscular Dystrophy, and late-stage Parkinson. This needs a considerable increase of our sustainable R&D budget to approximately € 400 million by 2025.
In order to strengthen our position in this dynamic environment, we will broaden the cooperation with partners (e.g., via in-licensing of products, technologies) – this trend is affecting the whole pharmaceutical industry.

Our corporate culture is important to drive changes. Patients and their needs are in the center of everything we do; delivering true benefits to patients is what we aim for. We can only achieve this by being an entrepreneurial specialist who thinks like an intelligent researcher and acts like a skilled businessperson at the same time. In 2015, we started to implement four mindsets which provide distinct guidance for the everyday conduct of each individual employee, and for us as a team at Grünenthal: when we are honest and courageous, innovative and clever, result-driven and value-adding, as well as caring and inspiring, we will be better at driving accelerated and sustainable growth – and both empowerment and accountability within Grünenthal will be strengthened at the same time.

Grünenthal’s thinking and actions are in the interest of future generations. In our Code of Conduct and our policy for Environment, Health & Safety, we commit ourselves to limiting the environmental impact of our business activities to a minimum and fulfill the requirements on occupational health and safety. This is achieved by means of consistent compliance with all applicable laws, internationally recognized guidelines, and industry standards. With many of the initiatives we at Grünenthal implement, we go beyond legal and official requirements.

This first Grünenthal sustainability report provides you with information about our efforts with regard to sustainability. It demonstrates that reporting as well as providing transparency for our stakeholders are of high importance to us – and are the reason why the report is based on the officially accepted standard GRI.

We are proud of our progress in 2015, and we know that there is still more we can do. In collaboration with our customers and partners, I am confident that we can further improve our efforts creating shared value for our company and society. We will continue to intensify our sustainability efforts and ensure future learning alongside our partners. We are and will remain committed to further improving the health of people around the globe.

Yours sincerely,

Prof. Dr. Eric-Paul Pâques
Chief Executive Officer

3 Chronic Pain: backgrounder – http://www.eccesspack.net/mnr/dynamic/2013/01/414863.pdf

4 IMS Health, WHO ODD, Grünenthal Market Research
Corporate governance refers to the entire system of managing and supervising a company. This includes the organization, values, corporate codes, and guidelines as well as internal and external monitoring mechanisms. A transparent and efficient corporate governance builds the foundation by which Grünenthal is managed and monitored – namely, in a responsible manner. This fosters the confidence that the owners of Grünenthal, patients and physicians, social insurance groups and other business partners, employees, and finally the community have in our company.

Grünenthal is a 100% family-owned company. The family shareholders appoint the members of the Supervisory Board (Beirat). The Supervisory Board appoints the members of the Corporate Executive Board and supervises and advises the board on management decisions.

We are an entrepreneurial specialist delivering true benefits to patients. With this company purpose, we emphasize that the main focus of our daily efforts is the patients in need: to improve the health condition of those who need analgesics to stop their pain. Beyond this, our entrepreneurial responsibility comprises much more. We are permanently integrating the continuously developing regulatory requirements into our business processes. We are striving towards good corporate governance by focusing on our Code of Conduct, which describes our attitudes and the practices every employee is expected to live by. It also describes the voluntary measures taken by Grünenthal, including those required by law, to ensure ethical and legal business conduct as well as the personal integrity of all employees.

Furthermore, our Code of Conduct instructs us on how to do things the right way and, in doing so, helps us to protect our patients, customers, employees, owners, and our own reputation. Our Code of Conduct is more than a simple guide to ensure we comply with laws and regulations. Rather, it encapsulates
Good Corporate Governance

our principles and ethics, encourages us to exhibit attitudes that reflect our purpose and our corporate culture. It includes, but is not limited to:

Integrity of Research & Development
We commit ourselves to honesty and objectivity in the interpretation of our nonclinical and clinical data, and to transparent and open communication with the regulatory authorities and the scientific community. We undertake all necessary steps for the best-possible commitment to executive care and pay strong attention to data protection and confidentiality with regard to patient data.

Responsibility of each employee
The Code of Conduct clearly defines the expected practices of our employees. Every employee is personally responsible for understanding and to complying with the Code of Conduct. Failure to do so may lead to disciplinary action up to and including termination.

Environment, Health and Safety
We profess that our business is always in accordance with prevailing regulations and laws with regard to environment, health, and safety. We offer our employees a safe and healthy working environment. We strive to make the use of our resources more efficient and responsible, including the reduction of any unnecessary waste.

Ethics and Compliance
Per definition, compliance is the state of being in accordance with established legislation, regulation, policies, guidelines, and/or specifications. Through our company purpose, mindsets, and compliance principles, we express our commitment to conduct all activities ethically; we provide guidance on defined measures and processes; we promote and acknowledge an ethical compliance culture; and we acknowledge adherence to international law and industry standards.

Quality Assurance
Quality is a cornerstone of our success. The high quality of our products, benefits, and processes ensure patient safety, competitive advantages for our company, and sustainability for our business.

Corporate Social Responsibility
Our society creates the basic conditions which enable us as a pharmaceutical company to engage highly qualified employees and develop our innovative medication and make them available to patients. As we want to give back to society in addition to our medicines, social commitment is important to us.

Beside our Code of Conduct, another tool has been implemented to offer specific guidance for the everyday practices of each individual employee and for us as a team at Grünenthal: our four "Mindsets". The mindsets also define our desired attitude and how to achieve this. To drive accelerated and sustainable growth as an entrepreneurial specialist, we need a corporate culture of living these mindsets, and to strengthen both empowerment and accountability within Grünenthal.

Innovative + Clever
There is an enormous amount of knowledge, competence, creativity, and ideas in our company. Everyone is asked to take a broad view of their responsibilities, to be open to take risks, and to be in a close dialogue with colleagues of other departments.

Honest + Courageous
To be open and self-critical, and to make clear-cut decisions are among the most important qualities of successful entrepreneurs.

Result Driven + Value Adding
When everyone feels responsible for the company’s success, we can achieve great things together.

Caring + Inspiring
In everything we do, we keep a close eye on what really contributes to the result, because we can only create value by focusing on the big picture and thinking in terms of the overall outcome.

In addition to these internal mindsets and requirements, Grünenthal is engaged in various institutions and organizations to
help improve sustainability and entrepreneurial conduct within the pharmaceutical industry, for example.

**Responsible Care Initiative (Germany and Switzerland)**

Responsible Care is the chemical industry’s global initiative to drive continuous improvement and achieve excellence in environmental, health, and safety performance. Responsible Care embraces the development and application of sustainable chemistry, helping our industry contribute to sustainable development while meeting the world’s growing need for essential chemicals and the products those chemicals make possible.

http://www.cefic.org/Responsible-Care/

**Charta der Vielfalt (Germany)**

The Charta der Vielfalt (diversity charter) is a corporate initiative to promote diversity in companies and institutions, with focus on recognition, appreciation, and integration of diversity into Germany’s business culture. Organizations shall create a working environment free of prejudice. All employees should be valued – regardless of gender, nationality, ethnic origin, religion, worldview, disability, age, sexual orientation, and identity.

http://www.charta-der-vielfalt.de

**International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)**

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry’s 1.3 million employees research, develop, and provide medicines and vaccines that improve the life of patients worldwide. IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

http://www.ifpma.org

**EFPIA**

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU’s 1,900 companies committed to research, developing, and bringing to patients new medicines that will improve health and the quality of life around the world.

http://www.efpia.eu

In addition, Grünenthal is a member of various local trade associations in most countries where we have an affiliate.
The Grünenthal Code of Conduct requires all Grünenthal employees to comply with the applicable laws, directives and internationally recognized industry standards and pharmaceutical trade association codes. It also describes the voluntary measures taken by Grünenthal. Our Code is more than a simple guide to ensure we comply with laws and regulations. Rather, it encapsulates our principles and ethics, encouraging us to exhibit attitudes that reflect our purpose and mindsets – in short our corporate culture.

In 2015, no fines or nonmonetary sanctions due to noncompliance with environmental laws and regulations were declared. There have not been any fines for noncompliance with laws and regulations concerning the provision and use of products and services.

Structure within the company

We are aware that a living compliance culture needs continuous training. Therefore, we have set up mandatory training courses for every employee. Amongst others, this includes training with regard to our Code of Conduct, Anti-Bribery/Anti-Corruption, conflicts of interest, and information security which have already been completed by most of our employees worldwide.

Employees’ responsibilities

In acting according to our Code of Conduct, our employees contribute to the constant improvement and development of Grünenthal’s compliance culture. Every employee has a personal responsibility to comply
Compliance

with our Code of Conduct. For employees with leadership responsibility, we expect to lead by example. As a leader, they drive the company culture, create the right environment, and set the priorities. Therefore, their commitment is vital to fostering Grünenthal’s ethical culture and compliant conduct.

Noncompliance with our Code of Conduct can create serious risks for Grünenthal and our patients, customers, shareholders, and employees. Therefore, failure to comply with the Code of Conduct may lead to disciplinary action up to and including termination.

Anti-corruption

Improper payments or any other form of corrupt business conduct by any of our employees, or by any of our business partners, to any private or public person or institution could expose the employee or the third party to civil and criminal prosecution, and may harm Grünenthal. Our employees should never offer or give any form of advantage with the intention to improperly influence business partners or the government, and never allow any of Grünenthal’s third parties to act in this manner. Related company standards are covered via policies, processes, and a third-party program covering our main third parties: from healthcare-specific (healthcare professionals, healthcare organizations, patients, and patient organizations) to vendors, partners, and customers. Started several years ago, we constantly record and monitor on an individual level each type and transfer of value to healthcare professionals, healthcare organizations, and patient organizations. Such transfers of values are already publically disclosed in countries where a disclosure requirement exists. As an EFPIA member, we self-disclose all healthcare-related transfers of values made since 2015 in each European country.

We perform a vendor due diligence on all our vendors to protect our company for liability and reputational damage caused by the incorrect conduct of vendors. We are not aware of any incidents of corruption in 2015.

Anti-competitive behavior

Grünenthal strongly believes that customers and society as a whole benefit from free fair, and open markets, and that is why we seek to be successful through the quality of our products and their competitiveness in the market. Therefore, we require all employees to comply with every applicable law and regulation regarding fair competition and antitrust.

Reporting responsibilities

It is every employee’s responsibility to promptly report any compliance issue, concern, or misconduct. We respect confidentiality. The information provided will be shared only when needed by those responsible for resolving this concern.

We protect our employees. Grünenthal absolutely prohibits any type of retaliation against any person who reports concerns or helped to report a concern. Concerns can be reported to the line manager or via our 24-hour compliance hotline.

Human rights

At Grünenthal, we guarantee equal employment opportunities and favor the professional growth of each individual employee.

The Grünenthal Code of Conduct forbids discrimination as defined in the ILO (International Labour Organization) core labor standards. Grünenthal does not tolerate discrimination or workplace bullying of any kind. This includes race, gender, religion, creed, nationality, disability, age, sexual orientation, physical or mental handicap, marital status, political views, or other characteristics protected by law.

Grünenthal aims to ensure a safe working environment for its employees. All forms of workplace violence, including threats, threatening gestures, intimidation, attacks, and similar forms of unacceptable behavior are forbidden. Employees as well as leaders have to report any identified deviation via normal reporting lines or by using the compliance hotline.

Employees are completely free to join trade unions, associations, and similar organizations. No rights with respect to exercising freedom of association or collective bargaining as defined in the ILO core labor standards and the UN Global Compact are subject to restriction at the Grünenthal Group.

There was no case of violation against freedom of association and collective bargaining in 2015.
Customer in Focus

Pain is the most common single reason why an individual consults a medical professional. In Europe, the core market for our pain products, one in five people is affected by chronic pain. The differentiation of the pain forms of manifestation is crucial for the treatment, since it provides relevant information about the cause of the pain and where it originates from. About 50% of European pain patients wait a minimum of two years to receive adequate treatment. Inadequate management of pain affects societies everywhere: there are nearly 500 million lost working days across Europe every year, and 19% of sufferers lose a job because of their pain.

The European Pain Federation (EFIC®) states that chronic and recurrent pain is a specific healthcare problem, a disease in its own right, while acute pain may be considered a symptom of disease or injury. Pain and especially chronic pain can have a significant negative impact on patients’ quality of life. Grünenthal is committed to changing pain: 15% of chronic pain patients in Europe are treated with a compound or product from our R&D.

Duration of pain

Acute Pain
- is caused by external or internal injury or damage
- intensity correlates with the triggering stimulus
- can be clearly located
- has a distinct warning and protection function

Chronic Pain
- is not associated with the causal event
- intensity no longer correlates with the causal stimulus
- becomes a disease in its own right
- has lost its warning and protective function
- is a special therapeutic challenge
- lasts longer than the normal duration of the acute disease

2 Wiffen P: Pain – there is a lot of it. Eur J Hosp Pharm. 2013; 20:1
4 IMS Health, WHO DDD, Grünenthal Market Research
6 Wiffen P: Pain – there is a lot of it. Eur J Hosp Pharm. 2013; 20:1
7 Benhamou D et al.: Pre-operative information on therapeutic options is only given in ~69% of cases. Pain. 2008; 136:134-41
8 Benhamou D et al.: Did you know that often pain is not assessed and recorded? Approximately 34 % of physicians say that post-operative pain is not assessed in their institution. Pain. 2008; 136:134-41
Customer in Focus

**Indirect economic impact**

Indirect economic impact arises primarily due to positive side effects of direct economic action. Grünenthal aims to achieve sustainable improvement in the quality of people’s lives through innovative solutions in pain medication: less pain → less absence time → more efficiency. There is no management approach to indirect economic impact in the narrower sense. Instead, the company works with various stakeholders to identify the best solution in each case.

**Effective pain treatment**

We at Grünenthal build on our long-standing experience in innovative pain treatment and development of state-of-the-art technologies to improve patients’ health and quality of life. We gear our entrepreneurial actions to the interests and health of pain patients. We want to better understand their unfulfilled needs and their various challenges in daily life. In this way, we can focus our R&D activities more intensely on those aspects that are of use to the patients, and thus, provide medication for individual needs.

Our portfolio covers a wide range of medicinal products for patients with chronic and acute pain. Since pain is very diverse, different types of pain require different treatment approaches. From the launch of Tramal in 1977 to our latest products, we have a proven history of bringing groundbreaking pain medicine to patients. Patients benefit from a growing range of therapeutic opportunities from Grünenthal – from acute to chronic, and from moderate to severe pain. This includes therapeutics with an innovative mode of action as well as products with novel pharmaceutical forms, thus, covering a broad range of pain indications.

Beside these global brands, Grünenthal sells a variety of regional and local brands for different medical applications. Especially in Latin America, Grünenthal also offers a broad portfolio of local products for the areas of women’s health and CNS.

Additionally, Grünenthal sells the active pharmaceutical ingredients tapentadol hydrochloride, tramadol hydrochloride, betahistine, and the innovative TRF technology INTAC® (Tamper Resistant Formulation).

Grünenthal strives to further expand its product portfolio to make even better therapeutic options available in the future.

The primary global brands of Grünenthal are:
Customer in Focus

Delivering benefits to patients

In order to create real added value for our patients, we like to think outside the box. We seek a dialogue with and bring benefits to the patients. In this way, Grünenthal is involved in many areas – particularly on the subject of pain. We are active in different initiatives:

- With the support of the European Pain Association (EFIC®), our initiative CHANGE PAIN® contributes to improving the situation of patients with practicable approaches to solving daily problems.
- As a pain specialist, we appreciate the fruitful exchange of information and experience with motivated young scientists. Together with the EFIC®, we are supporting them through the EFIC–GRÜNENTHAL Grant.
- Our initiative “My pain feels like ...” aims to improve communication between doctors and patients. The more detailed patients can describe their symptoms, the greater the possibility of effective pain relief.
- Under the concept The Societal Impact of Pain, we provide professionals working in the healthcare environment, pain advocacy groups, politicians, insurers, representatives of health authorities, regulators, and budget holders the possibility of exchanging information on the effects pain has on societies, health, and healthcare systems in Europe.
- Grünenthal supports the Member of the European Parliament Interest Group on Brain, Mind and Pain, an initiative of the European Federation of Neurological Associations (EFNA) and Pain Alliance Europe (PAE). These two patient-advocacy groups are aiming to encourage research into and access to innovative treatments, promote prevention and self-management approaches, decrease stigmas, and work together to improve quality of life for people living with neurological and pain disorders.
- Grünenthal has entered into an official partnership on the development and implementation of European Pain Patient Pathways Recommendations with Pain Alliance Europe (PAE), an organization representing chronic pain patients in Europe, and the Active Citizenship Network (ACN), an organization that promotes and supports citizens’ powers and responsibilities in policy-making.
- Grünenthal also collaborates with Active Citizenship Network (ACN) on collecting good practices for Chronic Pain: making the invisible visible.
- Furthermore, Grünenthal supports the annual EU Patients’ Rights Day aiming at improving the rights and treatment options for patients with chronic diseases.

Customer health and safety

Grünenthal is committed to serving patients and the health community with products that improve their lives and health. To ensure this, Grünenthal has covenanted itself to a corporate quality mission:

Grünenthal is aiming for the safe, reliable, and economical production and supply of high-quality pharmaceutical products. The company knows and fulfills the needs and expectations of partners, customers, and patients. The products are appropriate for their intended use. They comply with the requirements of product-specific marketing authorizations and current Good Manufacturing Practice (GMP), legal, and contractual regulations. The Quality System continuously develops. Our high GMP standards are the result of the implementation of recognized international and national standards and continual improvement of our system. The pursuit of this quality objective is the responsibility of management and requires the active participation and commitment of all Grünenthal employees.

Grünenthal operates a Pharmaceutical Quality System (PQS), implemented throughout the different stages of a product life cycle (pharmaceutical development, technology transfer, commercial manufacturing, and product discontinuation). The PQS facilitates innovation and continual improvement in terms of product quality, processes, variability reduction, and pharmaceutical quality-system enhancements and strengthens the link between pharmaceutical development and manufacturing activities.

Grünenthal has in place a suitable key-performance indicators system in order to monitor the effectiveness of processes within the PQS. The Corporate Executive Board ensures its global oversight including risks and issues to take on senior management’s ultimate responsibility to ensure an effective PQS is in place by focusing on Quality Management in regular review meetings.
Customer in Focus

Grünenthal applies Quality Risk Management as a systematic approach and process, in order to ensure the quality of active pharmaceutical ingredients and medicinal products during their life cycle and to identify and prioritize fields for continual improvement.

Grünenthal operates a system for implementing corrective and preventive actions resulting from the investigation of deviations, nonconformances, product rejections, complaints, recalls, and trends from process-performance and product-quality monitoring as well as resulting from observations from audits and regulatory inspections. A structured approach to the investigation process is used with the objective of determining the root cause. CAPA methodology is employed to promote product and process improvements and enhanced product and process understanding.

Grünenthal operates an effective change management system in order to properly evaluate, approve and implement the GxP relevant changes. The change management system promotes continual improvement and assures that there are no unintended consequences of changes; particularly, the impact on product quality and marketing authorization.

People employed by Grünenthal have been chosen very carefully for their intended function. All the personnel whose duties and activities could affect the quality of the product have appropriate education, experience, and periodic training.

An effective system has been established for the handling of customer complaints; product safety-related events and deciding on the measures to be taken, as well as an effective system for recalling products within a very short time and at any given time in the distribution network.

- Incidents of non-compliance with regulations resulting in a fine or penalty in 2015: 0
- Incidents of non-compliance with regulations resulting in a warning in 2015: 17 recalls
  - Seven due to quality issues
  - Three voluntary recalls (discontinuation of the business
  - Seven products have been involved in the recalls

Data Protection

Data Protection is part of Grünenthal's Information Security Program and the Data Protection-specific content is covered under our Code of Conduct. Data protection also includes customer privacy.

Grünenthal is committed to handling any personal data in a responsible way and in compliance with applicable laws. We do so by protecting them during the course of our business activities and by ensuring high standards of data protection in all Grünenthal operations worldwide.

Grünenthal as a company is responsible for ensuring the correct handling of personal data by Grünenthal itself as well as by any third party working on Grünenthal's behalf.

It is our duty to handle personal and sensitive personal data with due care, not only because it is a legal requirement, but even more importantly due to our deep respect for all of our stakeholders. In this respect, we are dedicated to restricting access to this information and using it only on a need-to-know basis, as well as destroying it properly as soon as we no longer need to retain the data.

In 2015, Grünenthal did not receive any customer-privacy complaints.
Innovation and Product Development

We at Grünenthal are passionate about being the innovators in Pain Relief Therapies. We are committed to developing ethical and innovative prescription pharmaceuticals with significant advancement for patients. Our R&D center is located at our headquarters in Aachen (Germany). About 600 employees work here in the area of R&D (incl. Preclinical R&D, Clinical Development, Regulatory Affairs, Drug Safety, and other support units). Additional R&D units are in Latin America (Santiago de Chile) and in the US (Morristown).

Grünenthal Innovation: Some key numbers

- >40 We have worked in the pain area for more than 40 years so we have the experience and dedication to develop new medicines for pain patients
- ~240 Our 2015 total R&D budget to maintain our infrastructure and to invest into new projects is about € 240 million
- ~600 About 600 colleagues work across all aspects of R&D that are required to take a compound from the idea to a medicine
- 330 We have filed around 330 patent applications over the last ten years to protect our novel ideas and compounds

Innovation is the core of our business. We aim to make a real difference to the lives of our patients, and to improve their quality of life permanently and perceptibly. We look for products that clearly differentiate from the current standard of care. Our sustainable investment in R&D is above the industry’s average with 20% of our revenues per year. As a result, we are setting an example and committing ourselves to innovation. Our core competence is pain, and we are striving to secure the product flow over the long-term. Above all, this requires the continuous development of the NCE (new chemical entity) and NTE (new technical entity) portfolio. Our aim is to deliver improved medications either in cases where insufficient treatment options exist, or where improvements in efficacy or safety/tolerability could lead to an overall benefit for patients.

We are intensively working towards finding new and improved ways of treating pain, solving unmet medical needs, and bringing beneficial products with fewer side effects onto the market.

One example of our innovative research is the development of the INTAC® technology, a novel tablet form which restricts manipulation due to its high mechanical stability and poor solubility, and thus impedes drug abuse. The abuse of scheduled opioids is a widely known problem, especially in the US. For Grünenthal, it is important to ensure that patients who rely on treatment with strong opioids have access to these substances. A logical solution was the development of a formulation which makes the products more difficult to abuse, impairs manipulation, and makes their use less attractive to drug addicts.

R&D: Pain and focused search fields

- Pain
- Inflammation (niches)
- Perioperative Care
- Cancer supportive care
- Focused & specialty drugs

Grünenthal’s successful business model

Grünenthal is expanding further beyond its core strength in pain management to indications in niches and is looking for new partnerships and licensing agreements to bolster the pipeline and existing product portfolios in Europe and Latin America as well as the US.

In 2016, Grünenthal will also enter the hospital market in Europe with Zalviso®, a preprogrammed, noninvasive device for the management of acute postoperative pain.
**Innovation and Product Development**

Grünenthal's vision for the future is aimed at targeting focused indications and indications with unmet medical needs where currently no treatments are available. Some of these markets include perioperative care (hospital), niches in inflammation, and orphan drug indications such as Morbus Duchenne (DMD). Grünenthal has a long track record of successful partnerships and wants to build on this to achieve maximum growth and revenues in its core pain business while expanding additional indications.

**Investment in innovation**

Innovation is core to generate sustainable revenues as basis for our commitment to R&D. We intend to considerably increase our R&D investment until 2025 up to € 400 million. We are planning to grow further so that we can continue to finance our R&D.

With the investment into our new research building at our headquarters in Aachen in 2015, Grünenthal is showing its strong commitment to innovation. This high-tech building provides the employees with a modern infrastructure to develop innovative drugs. It also underpins our purpose to deliver true benefits to patients and to strengthen our leading position as an entrepreneurial specialist. The substantial investment of more than € 39 million also allows long-term planning for R&D and is a bold indicator of the future of Grünenthal in Aachen.

**Patient safety**

As a patient-focused pharmaceutical company, high quality and safety are of importance for Grünenthal’s present and future success. We ensure protection of our patients through our integrated Quality Management System covering Good Clinical Practice (GCP) for designing, conducting, recording, and reporting clinical trials that involve the participation of human beings. Also, we ensure Good Laboratory Practice (GLP) in terms of the organizational process and the conditions under which nonclinical health and environmental-safety studies are planned, performed, monitored, recorded, archived, and reported. Compliance with this standard provides public assurance that the rights, safety and well-being of trial participants are protected.

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**Medical need for orphan drugs/rare diseases**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 in 2,000 patients affected</td>
<td>Grürenthal highly interested to enter into rare disease arena</td>
</tr>
<tr>
<td>&gt;6,000 rare diseases¹</td>
<td>Current focus on Duchenne Muscular Dystrophy</td>
</tr>
<tr>
<td>116 rare disease therapies with marketing authorization are granted by EU</td>
<td>1,605 orphan products in development¹</td>
</tr>
</tbody>
</table>

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¹ Source: [www.eurodis.org/about-orphan-drugs](http://www.eurodis.org/about-orphan-drugs)
Responsibility for Society

Our society creates the basic conditions which make it possible for us as a pharmaceutical company to employ highly qualified employees, develop our innovative preparations, and make them available to patients. We would like to give society something in return in addition to our medicines. For this reason, social commitment is important to us.

In 1957, Grüenthal launched products with the active ingredient Thalidomide. It turned out that this substance could damage unborn children in the womb. The Thalidomide tragedy is and always will be part of our company’s history. We feel a special responsibility for the people who were affected by Thalidomide and who still need support in their daily lives.

As an innovative pharmaceutical company, we concentrate our financial commitment on projects and organizations from the healthcare sector. The promotion of palliative care in particular and the hospice movement have been close to our hearts for decades. In 1998, Grüenthal founded the Grüenthal Foundation for Palliative Care in Germany. It is dedicated to the needs of people with incurable diseases and limited life expectancies. The foundation promotes science and research in the field of palliative care in the form of a Chair of Palliative Medicine at the University of Aachen. It also supports the care of seriously ill or terminally ill people. The aim is to preserve the quality of life and the dignity of affected people at the end stage of their lives. To offer effective analgesics with as few side effects as possible is one important part of the treatment of terminally ill people, because pain should not dominate the last days of their lives. Of even more importance are specially trained caregivers who are aware of the needs of the patients in this special situation. A lot has been done in Europe during the last decades, but there are still differences within the European countries and science continuously learns more about the individual needs of people at the end of their lives. In the meantime, further foundations have been set up in Spain, Portugal, and Ecuador.

We also feel connected to charitable organizations in the areas where our affiliates are located. This does not only occur by means of financial support, but also by means of the activities of our employees. These activities range from self-organized donation campaigns to personal help via our colleagues on-site. We encourage and support our employees in their engagement in volunteer activities.

Altogether, our engagement for society is an important in expressing our values and is deeply connected with our mindset of “Caring and Inspiring”.

All donation activities are compliant with the codex of the Freiwillige Selbstkontrolle der Arzneimittelindustrie (FSA) (voluntary self-regulation of the pharmaceutical industry in Germany).

In our Code of Conduct, chapter Social Engagement, we state clearly that we do not provide any political contribution. In our Code of Conduct, it is also stated that no value to political parties is allowed.

Our focus: palliative care and the hospice movement

Even when a life-threatening illness makes life difficult, there is often still room for a smile, a moment of happiness, or the fulfillment of a dream. Grüenthal supports individuals and organizations that commit themselves with heart and mind so that such moments become possible. Our core financial support is to people who accompany children with life-shortening illnesses. Bringing together children and hospice care is difficult: children represent life and the future; hospices dying and death. And yet in Germany alone, there are about 40,000 children with serious, life-shortening illnesses. They will not reach the average age for hospice patients. However, they need help and guidance of the type that hospices provide. The important difference between hospices for elderly people and a children’s hospice is that for elderly hospice guests, a hospice is somewhere they go right at the end of their lives. Most live there just a few days, maybe weeks, seldom months. They come to die.

By contrast, a children’s hospice assumes the role of a guide over several years of life. Due to serious illnesses, the children who go there have life expectancies that are markedly lower than those of their peers. They receive palliative care, they can escape their daily routines, and their families get some respite. And most return home after a few days. Often funding agencies are not set up for this – significantly more expensive – difference.

One of many initiatives Grüenthal has supported over the years is the “Oskar Helpline”, where people seeking help can get information and advice pertaining to children with life-shortening illnesses at no cost, 24 hours a day. It is not simply a matter of direct treatment, but also of care for their families: The parents are especially burdened with worry and the responsibility of caring for their sick children. Siblings often feel neglected. And even when a family has known for a long time that a child will die, the loss at the end is very hard to take.

To raise awareness of the special situation of children with life-reducing diseases and the difficult financing of children’s hospices,
Grünenthal has significantly supported the production of the Little Stars film campaign. By now, three films have been produced, introducing the daily life of a child, their hopes and dreams, and shows the burden for the other family members. The films are presented in cinemas and via Youtube.

Emergency relief – when employees and the company help hand in hand

In April 2015, an earthquake of magnitude 7.8 shook Nepal. As a consequence of the quake, more than 8,000 people died; tens of thousands were injured. The global relief effort kicked in quickly, but the cleanup work was made more difficult by the many aftershocks. The strongest occurred barely two and a half weeks after the first quake and again had fatal consequences for the small country. In total, more than half a million houses were completely destroyed.

Many employees of the Grünenthal Group expressed the joint wish to make a small, sustainable contribution to help daily life return to normal in Nepal. As a result, the company decided to work together with Habitat for Humanity Deutschland. Habitat for Humanity is an international aid organization with projects and representatives in more than 70 countries. The organization was founded in the USA in 1976. Its goal: to help provide shelter for people in situations of need worldwide by building modest and affordable houses. Over and above that, the organization is active in disaster preparedness and relief.

All Grünenthal employees worldwide could participate in the firm-wide effort in Nepal by making a donation. The amount donated was then matched by Grünenthal so that overall it was possible to transfer €66,000 to Habitat for Humanity. “We are happy that the idea was accepted so positively by the employees. The readiness to support those in need in Nepal was very high,” declares Dr. Heinz-Gerd Suelmann, Head of Global Human Resources. The firm’s donation was then used to build houses and local infrastructure in the Kavrepalanchok district in the Bagmati zone southeast of Kathmandu. “After the devastating earthquake in Nepal in April 2015, emergency help was initially the focus of the media. Based on our many years of experience, however, we from Habitat for Humanity know that the reconstruction that takes place after the initial injection of emergency aid is the more substantial part of the process, and must be undertaken with great care and farsightedness,” explains Christian Michalski of Habitat for Humanity. “With the Build Nepal program, we now plan to support 200,000 households across the entire country within three years.” The houses will be built with environmentally friendly, local materials to withstand vibrations from stronger earthquakes. Sidhi Maya Magar, the 71-year-old resident of a Habitat house, reported after the earthquake: “I was in the garden, harvesting vegetables, when the earth began to quake. [...] The house where I lived before suffered numerous cracks, but the Habitat house did not.”

The future residents of the houses obligate themselves not only to build just under 50 percent of their home themselves, but also to finance part of the construction costs. This money then flows into the financing of further houses. In this way, the Nepalese government, the strategic partner of Habitat for Humanity, would like to promote the reconstruction long-term.

Our participation in the Build Nepal project was not merely donating money. We started a broad internal communication about the situation in Nepal and we are still running a blog to keep our employees updated on the development in the Kavrepalanchok district. Engagement in the society is more than giving money – it’s about caring for the people.

This project is a good example for the cooperation between the company and our employees in situations of emergency relief.
Responsibility for Society

Thalidomide - a part of our company’s history
Almost 60 years ago, the then-new company Grünenthal introduced the active ingredient Thalidomide as a sedative, a move that brought about the Contergan tragedy. Today there are about 5,000 people who were born at that time with in some cases serious abnormalities. This tragedy is and always will be part of the company’s history.

Over the years, Grünenthal has made more than € 100 million available to those affected. Many of our licensing partners, often in cooperation with national governments, have likewise provided services to support those affected.

At the end of 2012, Grünenthal established another institution, the Grünenthal Foundation for the Support of Thalidomide-Affected People in order to improve the living conditions of those affected in a sustainable way.

Above all, the Grünenthal Foundation concentrates on the retention of mobility as well as having autonomy in one’s living situation.

Mobility is an important factor for participation in social life and it provides autonomy. People who suffer from abnormalities of the arms or legs generally cannot use public transport. As a result, they are dependent on their own vehicles. However, these vehicles must be expensively and individually adapted so that a person affected by Thalidomide can drive the car safely in traffic.

Not to have to ask others, but rather to be able to act on one’s own, is important for many. This also applies to being able to lead one’s life between one’s own four walls. People affected by Thalidomide are often dependent on help because of their physical limitations. The less they need to make use of this help, the better they can live with these limitations. That starts with personal hygiene and continues with meal preparation. For that reason, the Grünenthal Foundation supports the disability-compatible retrofitting of bathrooms, kitchens, and living rooms. Nowadays, there is an extensive selection of special assistive devices and alterations that allow people with disabilities to live at home as autonomously as possible.

Initiatives

<table>
<thead>
<tr>
<th>Year</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>2015</td>
<td>The Grünenthal-Stiftung zur Unterstützung von Thalidomid-Betroffenen has supported more than 600 requests from affected persons. The payments made by the Conterganstiftung (Contergan Foundation) to those affected amount to more than 600 million Euros.</td>
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<tr>
<td>2013</td>
<td>Grünenthal organizes a round table with representatives of those affected at which the concrete needs of the people and the possibilities for support are openly discussed.</td>
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<tr>
<td>2013</td>
<td>After a study by the Universität Heidelberg paints a drastic picture of the health situation of those affected by Contergan, the German federal government significantly increases the level of financial support provided to them.</td>
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<tr>
<td>2012</td>
<td>Grünenthal establishes the “Grünenthal-Stiftung zur Unterstützung von Thalidomidbetroffenen.” Grünenthal supports those affected by Contergan by assuming the costs of items provided and offers projects for sustainable improvements in the living situations of the affected persons.</td>
</tr>
<tr>
<td>2012</td>
<td>During the dedication of a Contergan memorial in Stolberg, the then CEO of Grünenthal, Dr. Harald F. Stock, apologized in the name of the company, the employees and the owners for the fact that for almost 50 years we had not found a way to reach out person to person, but rather had remained silent. After that, a dialogue with those affected by Contergan was started, and continues to this day</td>
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<tr>
<td>2011</td>
<td>Grünenthal starts a hardship initiative through which, for the first time, the enterprise offers support services to Contergan victims other than money payments to the Contergan Foundation.</td>
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<tr>
<td>2009</td>
<td>Grünenthal transfers a voluntary payment of 50 million euros to the Contergan Foundation. From this money, special annual payments are made by the Contergan Foundation to recognized affected persons.</td>
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<tr>
<td>2007</td>
<td>A first meeting between representatives of Grünenthal and the Bundesverband der Contergan-Betroffenen takes place. The goal is to join with the federal government to find better ways to care for those affected.</td>
</tr>
<tr>
<td>2003</td>
<td>After Grünenthal had supplied Thalidomide to the WHO for many years for use in leprosy hospitals, the supply of Thalidomide by Grünenthal was finally ended.</td>
</tr>
<tr>
<td>1990s</td>
<td>Discovery that Thalidomide has an anti-inflammatory effect on the immune system and inhibits the formation of new blood vessels. Use to combat serious illnesses such as AIDS and cancer.</td>
</tr>
<tr>
<td>1972</td>
<td>Grünenthal pays 100 million German marks (ca. 50 million Euros) to the government’s Contergan Foundation.</td>
</tr>
</tbody>
</table>
Employees

People are one of Grünenthal's vital strengths. They make the difference that makes our company special. We see our employees as the key to our success. To stay competitive, we need to continuously attract, hire, and retain the best and brightest talents worldwide.

We empower our diverse and committed people worldwide through our corporate culture, encourage lifelong learning and development, offer an attractive working environment, and ensure occupational health and safety. According to the Great Place to Work®, 79% of all employees consider Grünenthal a Great Place to Work®. This result shows our progress and areas where we can still improve. It is our professed goal to become a Great Place to Work and rank among the top employers in the countries and regions where we reside. The latest survey in autumn 2015 ranked Italy, Spain, Portugal, and Switzerland already being ranked as Great Place to Work. With this objective in mind, Grünenthal has created numerous incentives for its employees over the past few years. These incentives serve to promote employee motivation and satisfaction. At the same time, a working environment is created in which performance and innovation are supported and every employee has the possibility of being able to make a sustainable contribution for our patients.

Employment at Grünenthal

At the end of 2015, Grünenthal employed 5,264 people. The proportion of female employees globally at that time in 2015 was 53%; for first senior management level this figure was roughly 29% and for second senior management level 30%. The Supervisory Board (Beirat) consists of five men.

The average fluctuation rate (in terms of employees with permanent contracts, without natural departures, and long-term leaves of absence) was 5.2%. Including natural departures, it was 6.5%.

Grünenthal implements the currently applicable legal framework conditions. It also attempts in individual cases to find solutions that are as suitable as possible for the affected person and their team. 100% of all permanently employed women are entitled to maternity leave, and 51 women in Germany made use of this in 2015. More than 90% returned to Grünenthal following their maternity leave and were still at Grünenthal one year after their return.

In Germany, permanently employed men are entitled to paternity leave. At Grünenthal, 17 men made use of this in 2015. At the end of 2015, employees entitled to parental leave in Germany: 45 maternity leave without part-time, 50 maternity leave with part-time and 11 maternity protection period.

At the end of 2015, Grünenthal started to report a female ratio for the first and second level of senior management in Germany (Global Grade 14 and above). At this time, both ratios were around 30%, which fulfills the target.

Grünenthal has no personnel policy or employment practices providing for the preferential treatment of persons from local vicinities in connection with the hiring of members of management boards for the respective country organizations. However, Grünenthal would like to establish organizations at its production and sales sites that function on a local basis, which is why it always integrates locally appointed managers. For example, most of the sales companies in Latin America are headed by a managing director who has been recruited locally.

Approximately 1,000 employees, and thus around one-fifth of the workforce, are currently covered by collective agreements (e.g. collective labor agreements, wage agreements). The percentage is especially high in Germany, where more than 95% of employees at the production company are subject to a collective labor or wage agreement. There are no collective agreements with employees in Latin America (except from Chile, where some of the employees are members of a trade union with wage agreements) or other countries of the EU.

Competitive and fair remuneration system

Grünenthal pays market-rate wages, taking into account local circumstances and laws. In accordance with their qualifications, the majority of Grünenthal employees at the five production sites and at the sales companies are paid well above the minimum wage range. Stability and a high level of motivation among employees are important to Grünenthal. This is being encouraged at the new site in Chile, for example, by means of a comparatively attractive pay structure. The applicable requirements on minimum wages are well met. In 2015, salaries and social benefits amounted to € 360 million. The employees can also participate in the financial success of Grünenthal through a bonus system.

The Grünenthal Group sponsors defined benefit plans for its employees at all sites and affiliates. Grünenthal spends € 19.5 million per year on those liabilities. There is no special fund to pay-plan's pension liabilities. The old pension plan in Germany, which covered approximate-
Employees

In 2015, approximately 50% of Grünenthal’s employees, was closed in 2015. A new pension plan will be opened in 2016 which will cover 96% of Grünenthal’s employees in Germany.

Fair pay is guaranteed as follows: Determination of salaries, primarily according to function, evaluated in accordance with the grading process. A score is calculated based on the assessment criteria expertise, problem-solving, and accountability. The resulting number of points is the basis for determining the salary. According to the annual binding survey of all Grünenthal Group companies, no differences between the basic salaries of women and men exist anywhere within the Group.

Support for better compatibility of work and family

A good balance between work and private life is a decisive basis for satisfaction and long-term productivity from which employees and the company equally profit. We support our staff in fulfilling family and professional requirements and challenges to the same extent.

In Germany, since the first participation in the Audit berufundfamile in 2010, various initiatives have been put in place, such as flexible working hours, part-time models, home office, part-time nursing care with a voluntary care allowance, children’s holiday fun and games. Approximately 1,800 employees at Grünenthal in Germany can take advantage of these family-conscious measures. In 2015 in Germany, a joint company kindergarten opened. It shows that helping employees to combine a career with family life is not just a slogan for us.

Measures for health and social care

Grünenthal attaches great importance to a high level of health and safety for its employees. To this end, Grünenthal cooperates with authorities, trade unions, and employers’ liability-insurance associations on a country-specific basis. Agreements exist at all production sites and individual sales companies with parties such as trade unions and employee representatives that normally cover topics such as personal protective equipment, complaints procedures, regular inspections, education and further training, and the right to refuse unsafe work.

Personal development options

We want our people to strengthen their personal skills and competencies. This will enable each of us to reach our full potential and contribute to the realization of our personal dreams and aspirations.

Learning and development affects everyone and is a lifelong process. All instruments at Grünenthal seek to support managers to identify and strengthen the critical capabilities and competencies of all our employees. Every employee is responsible for his/her own development. Developing people is also an imperative leadership task.

To achieve this, constructive feedback is a basic requirement to systematically identify strengths and development needs. We see learning and developing as an integral part of daily work; off-the-job learning measures are complementary measures to inspire or provide background. Roughly 80% of learning should happen on the job, and 20% off the job. Global HR develops global frameworks and tools for learning and development, and provides transparency on adequate formats and instruments to develop. It organizes a range of relevant seminars and training courses internally and offers guidance to select external seminars/training training courses.

- In 2015, around 95% of all employees group-wide received appraisal interviews where development opportunities were also identified and discussed.
- New employees are introduced to the company and its products through various job-orientation programs on joining the company. These range from individually designed introduction meetings in various departments to the one-week basic course that provides practical knowledge about Grünenthal in small groups.
- Young people can start their careers at Grünenthal Germany and Switzerland with a commercial, industrial, or technical apprenticeship. The aim is to impart all the skills that are required for apprentices to pursue their chosen careers in a professional, independent, and responsible manner.
- Compliance trainings are mandatory for all employees. Regular training is a requirement of cGMP, the EHS standards, and others and are mandatory to the employees working in the manufacturing process.
- Talent pools ensure prospective candidates for management positions for the respective business areas, for example R&D Scientific Expert Talent Pool, EU Talent Program, Grünenthal Executive Program.
Production

Global Product Supply procures from 1,200 suppliers’ 6,200 raw materials, excipients, intermediates, and packaging materials worldwide. Approximately 1,500 employees in five production sites produce finished pharmaceutical products for all Grünenthal affiliates. Grünenthal provides production services to contract manufacturing customers and active pharmaceutical ingredient customers to make greater use of its capacities and yield an additional contribution to the result.

Grünenthal forms part of the value chain in the pharma industry. It has significant indirect economic impacts downstream on the customer side at wholesalers, pharmacies, hospitals, and physicians, as well as upstream at suppliers and transport companies. Continuous investment in five production plants in Europe and Latin America as well as the logistics center in Germany strengthen these individual economic areas.

The Group’s cost of materials in 2014 was €350 million. The company does not have its own transport fleet and contracts external transport companies for logistics services.

Precautionary principles

The precautionary approach plays an important role for Grünenthal as a company with own production sites. This approach is defined in the Grünenthal Code of Conduct.

The production sites and logistics in Germany, Switzerland, Italy, and Ecuador as a whole work with an integrated management system and have a Group Certificate in accordance with ISO 14001 (environment management system) and OHSAS 18001 (occupational health-and-safety management system). Quality is covered by following the cGMP guidelines.

The production site in Chile will certify OHSAS 18001 in 2017 and ISO 14001 in 2018. After successful certification of the management systems, it will be integrated in the Group Certificate.

Individual sites will integrate the ISO 50001 standard for energy management in the following years.

In operations, preventive approaches are implemented for environmental protection, energy efficiency, occupational health, and safety and quality assurance.

In line with the best-in-class approach, long-term goals were drawn up. For example, by the year 2020 the aim is to reduce absolute CO₂ emissions in the Swiss plant by 39% compared with the base year 2013.

In all production sites, we will reduce the accident rate LTIF (Lost Time Injury Frequency: accidents per 1 million hours worked) to <6.7.

All five production plants started introducing the Grünenthal Production System in 2015. Operational Excellence standards in production will be uniformly implemented using methods such as SPS (Systematic Problem Solving), SS (Workplace Organization Methodology), OEE (Overall Equipment Effectiveness), SW (Standard Work), and DLM (Dashboards, Leadership, Meetings).

Requirements for suppliers

Grünenthal has relations with a total of more than 1,200 suppliers worldwide. It is not possible for us to inspect all suppliers to the same extent by auditing them on-site. Therefore, requirements for components and services, especially quality requirements, are available in written form. Suppliers of materials, components, and services are initially evaluated and regularly reevaluated following a risk-based approach considering their ability to meet specified requirements. This evaluation includes audits, where appropriate. Components and services are purchased only from formally approved suppliers. The quality standard of all products marketed by Grünenthal, are evaluated at least annually to determine the need for changes in product specifications, manufacturing procedures, or control procedures.

Ensuring employees’ health and safety

Ensuring the health and safety of our employees at work is a Grünenthal priority. In our company policy for the area of Environment, Health & Safety (EHS), we commit ourselves, among other things, to follow our company responsibility and continuously improve our health-and-safety guidelines. With support from our health and occupational-safety management system in accordance with OHSAS 18001, we achieve a high safety level and ensure that all relevant legal requirements are fulfilled.

Since 2009, a network of EHS managers has been practicing active occupational-health-and-safety procedures at the production plants¹ to ensure employees’ health and safety. They systematically assess the risks (handling of hazardous substances, noise, vibration, etc.) and determine adequate measures. These activities are combined in an Industrial

¹ The five production sites cover 59.3 % (3,122 FTEs) of all employees of Grünenthal.
Production

Hygiene program. The accident rate (Lost Time Injury Frequency; accidents/1 million hours worked) could be reduced from 16.8 in 2008 to 4.6 in 2015. The persons in charge at all locations meet at least once every year at a global EHS meeting to share their experiences and best-practice advice.

Each of the five production sites has an EHS team. All (100%) of the employees at the production sites (3,122 or 59% of the whole of Grünenthal) are represented through an occupational-health-and-safety committee in which employer and employee representatives can discuss occupational-health-and-safety issues. As a rule, national standards for the country concerned are implemented.

At Grünenthal, there are a few operational activities involving a particularly risk of contracting a serious illness or with a high incidence of illness.

- Employees in manufacturing, in analytical laboratories, in R&D, and in maintenance handle hazardous substances or equipment contaminated with hazardous substances. Grünenthal runs an Industrial Hygiene program to ensure the safe handling of hazardous substances and to mitigate the risk of occupational illnesses.
- Employees in manufacturing, in maintenance, in logistics, and in warehouses are exposed to potential injuries to a particularly significant extent due to their handling of heavy weights or working under noisy conditions. Grünenthal provides adequate devices, personal protection equipment, and performs training on these special topics.

Protection of the environment

Active environmental protection is self-evident for Grünenthal. In our company policy for the area of Environment, Health & Safety, we commit ourselves, among other things, to use our resources in a sustainable manner and to avoid the generation of waste where possible. By using our environmental management system in accordance with ISO 14001, we ensure that we adhere to all relevant legal regulations.

Consumption of energy

The consumption of energy in the form of electricity, combustibles, and fuels represents Grünenthal’s greatest environmental impact and generated costs of € 9 million in the five production sites in 2015. Since 2013, energy management has been practiced systematically in production, including regularly monitoring of energy consumption. Individual sites will integrate the ISO 50001 standard for energy management in the following years.

Grünenthal generally uses energy purchased externally. The direct energy carriers (Scope 1) include extra-light heating oil, natural gas, and the fuels diesel and gasoline.

At Grünenthal, only electricity consumption is significant for indirect energy consumption (Scope 2), and it simultaneously represents the greatest environmental impact.

In 2015, the five production sites consumed 42,797,178 kWh of electricity for their operational activities. In the same time frame, they consumed 88,232 liters of heating oil (= 977,614 kWh) and 4,907,442 m³ of gas (= 55,454,094 kWh). In total, the five sites consumed 99,228,886 kWh of energy in 2015.

Currently, we have only limited data about consumption of the fuels diesel and gasoline. The 310 company cars in Germany covered a distance of 9 million kilometers in 2015. For this distance, they used 580,000 liters of diesel (> 95% of the car fleet in Germany has diesel engines). This is equivalent to approximately 5.7 million kWh.

Reduction of energy consumption

Since the first publishing of the Grünenthal Energy Policy in 2012, the systematic measuring, collecting, and analysis of energy-consumption data in the production sites has started. This led to first energy efficiency projects in Grünenthal.

1 The five production sites cover 59.3 % (3,122 FTEs) of all employees of Grünenthal.
Production

Concrete examples show the clear efficiency gains that the reduction in relative energy consumption has been contributing to for years.

- In 2016, a combined heat-and-power station will be in use in Aachen. This plant will have a capacity of approximately 2 MW_{\text{thrm}} and 2 MW_{\text{elec}}. It is expected to run 8,000 hours a year. The electricity generated by the plant (16 GWh) will feed into the transmission grid and the resulting heat (16.5 GWh) can be used in production and heating systems. The efficiency of the plant will be approximately 85%.
- Since the end of 2012, a photovoltaic plant has been installed on the roof of building 605 in Aachen. Since this time, it generated approximately 100,000 kWh of electricity.
- Another renewable energy source is used in one office building on the campus in Aachen, Germany. A geothermal plant was installed in 2014 and is used for heating and cooling the offices. Compared to other office buildings on the campus, the KPI kWh/m² could be reduced by about 50%.
- On the Italian site, we installed a heat exchanger for steam blow-down.

Consumption of water

Grüenthal mainly uses fresh water from the public water system. Our production site in Ecuador has its own groundwater source for their water consumption, and our production site in Switzerland uses its own groundwater source for cooling.

A huge amount of water (900,000 m³) is used at the Swiss site. This water is withdrawn from a groundwater stream under the site, used to cool down the API production, and is reverted to the groundwater stream without any contamination. By this way, an energy amount equal to 4,380,000 kWh can be saved.

Grüenthal production plants’ water consumption does not place a considerable burden on water sources, as defined in the GRI guidelines. Only the treated waste water at the production site in Ecuador (22,871 m³) is reused to water the green area on-site. All the other waste water of the production sites (102,126 m³) flows into a river nearby after treatment.

Handling of emissions

Currently, we know only a part of the CO₂ footprint of Grüenthal. The direct and indirect emissions due to energy consumption in production are known. However, the emissions in the value chain before and after the production processes are unknown. Also, the emission due to the use of cars by sales representatives and management’s use of other modes of transport for travel, or due to energy consumption for heating and cooling in the affiliates are only partially known.

For combustion processes on the production sites 56,431,708 kWh fossil energy (oil and gas) have been used. This leads to direct greenhouse gas emissions (Scope 1) of 13,171 to CO₂.

In Germany, 310 company cars covered a distance of 9 million kilometers in 2015 and used 580,000 liters of diesel. This is equivalent to approximately 1,500 to CO₂.

On the production sites, 42,797,178 kWh of electricity was used. This led to an indirect greenhouse gas emission (Scope 2) of 13,040 to CO₂.

The production site in Switzerland agreed to a CO₂-emission reduction with BAFU (Swiss environment agency). The goal is to reduce CO₂ emission by 39% by 2020 according to the basis measured in 2013. In 2015, the CO₂ emission was 3% higher than planned due to higher production volumes.
Production

Quality Management System

Grünenthal’s quality organization ensures the quality of the products by a globally uniform, comprehensive complete and professional management team in accordance with GMP standards. Successful audits concerning GMP and EHS guarantee proper operation.

The mission of Global Drug Safety is to create safety in Grünenthal by ensuring protection of our patients through identifying, controlling, and mitigating safety risks. It is of paramount importance to ensure a favorable benefit-to-risk balance for all Grünenthal medicinal products throughout their entire life cycle.

Therefore, Grünenthal maintains and continuously develops an effective, global, quality-assured pharmacovigilance (PV) system which ensures patient safety by informing about side effects. The PV system is in concordance with applicable legal, regulatory, and ethical requirements. One key objective is the identification of new or changed safety risks associated with any Grünenthal medicinal product, as well as communication and minimization of these risks. For this purpose, all relevant sources of safety information are taken into account, including individual case safety reports (ICSRs), aggregated data from active surveillance systems, studies, and information literature.

Current GMP guidelines also require clear product information and labeling. In 2015, Grünenthal had no incident of noncompliance with regulations concerning products and service information and labeling resulting in a fine or penalty, in a warning, or with voluntary codes.

Greater security against counterfeit drugs

Counterfeit products could pose a serious threat to patients’ health, since they can contain abnormal doses of active ingredients or harmful substances. We at Grünenthal are working to put a stop to drug counterfeiting of Grünenthal products. In accordance with an EU directive against counterfeit drugs, our prescription-drug packages will be provided with a tamperproof feature and a unique serial number (Data Matrix code). This combination provides the maximum protection. In 2015, we prepared our machinery, packaging production lines, and IT infrastructure for conversion to the new system.

Risk management

An extensive system for the control and management of all risks involved in business activities is in place throughout the group. Integrated-risk-management processes are in place in most departments. Risks with a possible financial damage larger than € 500,000 will be reported to the global Risk Management System. Four times a year, a global risk report will be created and presented to the Corporate Executive Board and the Supervisory Board (Beirat).

In case of an incident on a production site, local emergency-management teams handle this event in cooperation with the communal action forces. If an incident is becoming a crisis, local crisis-management team’s also handle this situation. If a crisis gets bigger and affects Grünenthal as a whole, the corporate-crisis-management team is responsible in cooperation with the local crisis teams. After an incident, it is the goal to get back to daily business as fast as possible. Here, a Business Continuity Management system is in place.
About This Report

The 2015 Grünenthal Sustainability Report was created in order to provide transparency for stakeholders who determine and/or are affected significantly by Grünenthal’s business/activities. Grünenthal based this sustainability report on the Global Reporting Initiative (GRI) guidelines. GRI is a nonprofit, multi-stakeholder organization that provides companies with a systematic basis for informing stakeholders on corporate responsibility in a clear and comparable manner (www.globalreporting.org). This is the first time Grünenthal has utilized GRI sustainability reporting guidelines for a sustainability report and this report is in accordance with the latest GRI G4 Guidelines – Core option. The report has undergone and successfully completed the GRI Materiality Disclosures Service (see Organizational Mark in the GRI Content Index on page 29). This report has not been externally audited. However, various individual processes, results, and indicators are inspected in detail by external parties:

- Financial reporting is audited by external auditors.
- The production sites and logistics as a whole work with an integrated management system and have a Group Certificate in accordance with OSHAS 18001 (occupational-health-and-safety-management system) and ISO 14001 (environment-management system).
- Individual sites will integrate the ISO 50001 standard for energy management in upcoming years.
- On-site audits (compliance, quality, environment, health and safety) are carried out by Grünenthal experts (GIM, GQA, global EHS)
- Additional external audits, which check part of the aspects (e.g. cGMP audits by customers or authorities, SGS-audits for EHS, finance audits, etc.), have been performed.

This sustainability report includes the entire Grünenthal Group and covers the period from January 1 to December 31, 2015. Grünenthal will publish a sustainability report bi-annually. A comprehensive Materiality Analysis based on GRI aspects resulted from a series of workshops within the management team and defined the content of this report. The GRI aspects that Grünenthal identified as material in the economic, environmental, and social dimensions can be found in the GRI Content Index on pages 30 and 31. The material aspects listed are relevant for Grünenthal’s operations and stakeholders as they can influence business success. Economic, environmental, product-related, and human-resources topics found to be material are also relevant outside of our operations, such as the local communities where we operate or the different parts of our value chain.

Grünenthal’s key stakeholders have been identified as important for systematic stakeholder dialog as they fulfill one of two criteria: either the stakeholder group exerts a strong influence on the economic, environmental, or social performance of Grünenthal and/or the stakeholder group is strongly affected by the economic, environmental, or social performance of Grünenthal. Grünenthal’s key stakeholder groups include: patients and patient organizations, healthcare professionals and healthcare institutions, payers, the owners and Supervisory Board (Beirat), banks, the media, employees, trade unions, neighbors, municipality, research institutes, suppliers, transport companies, competitors, associations, interest groups, nongovernment organizations, the general public, as well as authorities and regulators.

Systematic dialog with stakeholders helps Grünenthal identify possible conflict issues and opportunities for continued development, and it allows Grünenthal to respond to these issues and opportunities efficiently. At the national and international levels, the Grünenthal Group and its affiliates maintain relationships with organizations and institutions in respective countries that provide direct requests and suggestions to the company. For important topics that stakeholders introduced and were subsequently addressed by Grünenthal, see pages 16 and 19.
# GRI Content Index

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