

The background is a teal color with a subtle grid pattern. A large, semi-transparent '50' is overlaid on the top half of the page. The '5' is on the left and the '0' is on the right. The '0' is a thick-lined circle.

Annual Report 2016



Our ultimate goal is to enhance the quality of patient care and human well-being.

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Steady growth, strategic acquisitions and significant investments were a great way to celebrate our 50th Anniversary



Jordi Rubiralta
President of WerfenLife

We asked Jordi Rubiralta, the President of WerfenLife, to tell us about the most relevant highlights of 2016 and the overall expectations for 2017.

In your own words, could you sum up the highlights of 2016?

The year 2016 was an exceptional one for many reasons. We completed the acquisition of Tem, an expert in viscoelastic technology and patient blood management at point-of-care, and negotiated the acquisition of Accriva Diagnostics, a global leader in *in vitro* diagnostic (IVD) blood testing at point-of-care. These acquisitions were significant strategic actions that reinforce our focus, commitment and leadership at the meeting point between Hemostasis and Critical Care where we occupy a unique position in the global IVD field by leading in both specialties.

2016 also marked the 50th Anniversary of WerfenLife. We have come a long way since our early days to the world-class company we are today. I feel proud when I think about the progress we have made and the results we have achieved during these 50 years of growing together.

Did you launch any new products?

We launched several new products. Among them, in the Hemostasis area, various HemosIL[®] reagents such as the HemosIL[®] ReditPlasTin, the HemosIL[®] AcuStar VWF:CB, and the

HemosIL[®] Apixaban Testing Solution that will significantly strengthen our Hemostasis solutions portfolio. Other launches include for example the HemoHub[™] Intelligent Data Manager V1.3, an information management system for Hemostasis laboratories.

In the Autoimmunity area, we launched the QUANTA-Lyser[®] 4000 – an important addition to our range of innovative instrumentation for autoimmune diseases. ⁽¹⁾

Could you summarize the most important figures of 2016?

Financially, we had a year of steady growth. Our sales reached 1.19 billion euros, representing a 5.1% growth over 2015. All geographical areas also grew with reference to 2015 which makes us especially proud. ⁽²⁾

How about investments?

In 2016, we invested 77 million euros in R&D. Another indicator of our strong commitment to innovation is the fact that 11% of our global workforce is dedicated to research and development functions.

The move to the new facilities of Biokit ⁽³⁾ in Lliçà d'Amunt (Barcelona, Spain) where almost 400 workers will be based, was also initiated. The new site of approximately 25,000m² represents an investment of 55 million euros. We are confident that this will

allow us to transition our present and future ideas into even better solutions. In addition, we completed the move to our new Iberian Peninsula logistics center in Tarancón (Cuenca, Spain) in early 2016. These facilities that cover around 14,000m² offer us closer proximity to our customers and logistics operators and thus help us lower our delivery times. Furthermore, they have increased our local operational capacity by 50%.

What is the outlook for 2017?

The outlook for 2017 is optimistic and we feel very confident about the future. Our main objectives will remain unchanged – we will focus on R&D, we will continue to raise the bar in our areas of specialization and to drive even better results. Above all, we will make sure that we uphold best practices now and in the future.

Our sales workforce will grow significantly in North America and emerging markets like China. This will help us strengthen our position and reach our full potential in these highly competitive markets. Due to our strategic acquisitions of Tem and Accriva Diagnostics, we will be able to strengthen our leadership and expertise at the meeting point between Critical Care and Hemostasis worldwide.

Furthermore, we will invest in the development of a new industrial center of 10,000 m² for Leventon ⁽⁴⁾ in Sant Esteve Sesrovires (Barcelona, Spain).

In your opinion, what sets WerfenLife apart from others?

I believe that the keys to our success lie in the strong commitment to R&D, our well-structured international expansion and the successful acquisitions we have realized throughout our 50-year history, along with the passion and commitment our employees demonstrate on a daily basis. We build upon decades of experience in creating meaningful solutions to our customers, and we are committed to finding innovative ways to benefit the society of today, and of the future.

Finally, what do you see as the ultimate mission of WerfenLife?

Together we are pursuing the quest of improving the quality of life of millions of people. Through our specialization in healthcare technology – IVD and Medical Devices – we contribute to a healthier society worldwide. We cover the full cycle of people's lives, from pregnancy to birth, from childhood to adulthood, including illnesses and surgical interventions, supporting the well-being of people during every stage of their life. As we grow with them, we also grow as an organization, as professionals, and as human beings.

(1) Specific product information on pages 20-21 (Hemostasis) and 24-25 (Autoimmunity).

(2) The growth is expressed in constant currency terms.

(3) Biokit belongs to Werfen, the IVD division of our business.

(4) Leventon belongs to the Medical Devices division of our business.

WerfenLife is dedicated to research and development (R&D), manufacturing and distribution of highly specialized Healthcare Technology – *In Vitro* Diagnostics and Medical Devices.

BUSINESS DIVISIONS

WerfenLife has two business divisions: Werfen -IVD- and Medical Devices.



AUSTRALIA, AUSTRIA, BELGIUM, BRAZIL, CANADA, CHINA, COLOMBIA, CZECH REPUBLIC, FRANCE, GERMANY, HONG KONG, HUNGARY, INDIA, INDONESIA, ITALY, JAPAN, KOREA, LITHUANIA, MEXICO, POLAND, PORTUGAL, RUSSIA, SOUTH AFRICA, SPAIN, THAILAND, THE NETHERLANDS, TURKEY, UAE, UK, URUGUAY, USA

Privately owned, global corporation headquartered in Barcelona, Spain.
Direct affiliates in over 30 countries, operating in more than 100 territories via distributors.

WERFENLIFE

IN VITRO DIAGNOSTICS

- Werfen**
- Instrumentation Laboratory**
A Werfen Company
- Inova Diagnostics**
A Werfen Company
- Biokit**
A Werfen Company

New Acquisitions

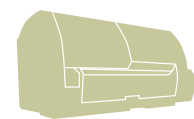
- tem®**
Healthcare Testing Control
- Accriva**
diagnostics

MEDICAL DEVICES

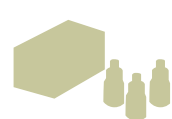
- Leventon**
A WerfenLife Company
- Izasa Hospital**
A WerfenLife Company
- Nicolai**
A WerfenLife Company
- Comesa Poland**
A WerfenLife Company
- Comesa Hungary**
A WerfenLife Company
- Comesa Austria**
A WerfenLife Company
- Medicinália Cormédica**
A WerfenLife Company
- Izasa Scientific**
A WerfenLife Company

OUR SOLUTIONS:

In Vitro Diagnostics



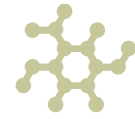
Analyzers



Reagents

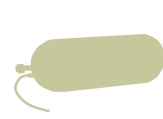


Software



Biomaterials

Medical Devices



Infusion Systems

IVD

Non-invasive tests performed on biological samples, like blood, urine or tissue, to diagnose, monitor or rule out a disease.

In vitro diagnostic products include e.g. reagents, instruments, and systems. These products are used in the collection, preparation, and examination of specimens taken from the human body. *

Medical Devices

Instruments, machines, appliances .../... intended to be used for diagnosis, prevention, monitoring, treatment or alleviation of disease or injury. **

* Source: US Food and Drug Administration, 2016.
** Source: World Health Organization, 2016.



OVERVIEW

CORPORATE SERVICES

WerfenLife is a global corporation consisting of leading R&D, manufacturing and distribution companies. The following corporate services exist to ensure synergies are maximized and best practices are shared throughout the organization.

MANAGEMENT

The talented leaders who define our strategy and push us toward our ultimate goal of enhancing patient care and human well-being.

HUMAN RESOURCES

The strategists who strive toward intelligent hiring and ensure our talented people are taken care of from "hire to retire".

FINANCE

The business partners who keep us on track with our strategy on revenues and spending.

INFORMATION SYSTEMS AND SERVICES

The developers of the highest quality IT solutions that help us work in an efficient and secure way.

CLINICAL SOFTWARE

The specialists who help enhance the quality of patient care and facilitate information management in hospitals, laboratories and other healthcare facilities.

QUALITY

The regulators who go the extra mile to reach the highest quality standards, making sure we deliver only the best.

AUDIT AND COMPLIANCE

The drivers of ethical behavior who make sure we do not just comply with rules, policies and regulations but take a step beyond.

LEGAL AND TAX

The experts who help us protect our interests and accomplish our goals.

LOGISTICS

The architects behind the efficient movement of our goods who make sure we always keep our customers satisfied.

PLANNING

The trackers of our performance who help us reach our objectives and plan ahead.

IMAGE AND COMMUNICATION

The brand ambassadors who identify our key messages and help communicate them both internally and externally.

OVERVIEW

CORPORATE GOVERNANCE

Board of Directors

This primary decision-making body is responsible for the administration and representation of WerfenLife. Its main accountabilities include:

- Determining the overall strategy of WerfenLife as well as its economic and financial objectives.
- Defining corporate plans and policies.
- Overseeing the development of the business.
- Ensuring the future viability and competitiveness of WerfenLife.
- Guaranteeing adherence to the highest ethical business conduct standards.



Jordi Rubiralta
(President) ¹

José Luis Rubiralta
(Director) ²

Xavier Rubiralta
(Director) ³

Marc Rubiralta
(Director) ⁴

Carlos Pascual
(CEO) ⁵

José Luis Martín
(Executive Director) ⁶

Germán Castejón
(Independent Director) ⁷

Miquel Roca
(Non-Director Secretary) ⁸

Executive Committee

This committee has full executive power corresponding to WerfenLife Board of Directors expressly and permanently delegated, with the exception of powers that cannot be delegated under the law or bylaws.

Jordi Rubiralta
(Chairman)

Marc Rubiralta
(Member)

Carlos Pascual
(Member)

José Luis Martín
(Member)

Audit and Control Committee

This committee reports directly to the WerfenLife Board of Directors in order to monitor and report on activities related to Compliance and WerfenLife Code of Ethics, internal and external audit and risk management.

José Luis Rubiralta
(Chairman)

Marc Rubiralta
(Member)

Germán Castejón
(Member)

Miquel Roca
(Non-Member Secretary)

Compliance Officer

This officer is responsible for preparing, monitoring and managing all topics related to Compliance and WerfenLife Code of Ethics, including Compliance applied to existing internal and external rules and regulations.

Albert Garicano
(Compliance Officer)

QUALITY MANAGEMENT

Quality is one of the most important features behind the success of WerfenLife.

We strive to meet the highest quality standards across all business divisions and geographical areas. WerfenLife has 54 ISO certificates which is an indication of our constant commitment to quality, sustainability, and our customers.

ISO standards are issued by the International Organization for Standardization (ISO). Their purpose is to ensure the safety, reliability and quality of products and services.



ISO 9001

It ensures that the organization provides products and services that consistently meet customer and regulatory requirements, and that the organization consistently aims to enhance customer satisfaction.

ISO 9001 covers all product/service related processes like purchasing, customer orders, HR, warehousing, technical service, post-market activities, training, etc. This is the most extended ISO certification worldwide.

ISO 13485

It ensures that the organization provides medical devices and related services that consistently meet customer and regulatory requirements. All WerfenLife manufacturing sites are certified with this standard.

ISO 14001

It ensures that the organization strives to manage its environmental responsibilities in a systematic manner and in compliance with international and local environmental regulations.

Source: International Organization for Standardization, 2016.

OVERVIEW

OUR VALUES



DELIVERY OF RESULTS

Quality & Excellence, Customer Focus

We are thoroughly committed to accomplishing our mission and strategic long term goals. We are dedicated to exceeding our customers' and stakeholders' expectations and going the extra mile that sets us apart from others.

LEADERSHIP AND MANAGEMENT

Teamwork, Innovation

We are dedicated to solid leadership and collaborative teamwork that allows us to carry out the strategy and the mission of our company in a purposeful way. We continue to invest in innovation as it is the catalyst for the growth and success of our business and the key to our competitive advantage.

INTEGRITY

Honesty & Humility, Respect for People

We always live up to our words. We say what we mean and we mean what we say. We are direct and straightforward and we deliver according to the expectations we have generated, allowing us to build trust and credibility among our customers and stakeholders.



WerfenLife employees are our most valued and important asset, representing our company’s mission and values in their day-to-day interactions with our stakeholders.

Recognizing this, we are firmly committed to the idea of looking after our people throughout their entire employee life cycle- “from hire to retire” – we call this our **Integrated Talent Strategy**.



Employees*		2016	2015
	Men	2,540	2,763
	Women	1,848	1,587
	Total	4,388	4,350

R&D		2016	2015
→	Global Workforce	11%	10%

Activity		2016	2015
→	Management & Administration	11%	11%
→	Sales	45%	44%
→	Operations	44%	45%

Geographical Area		2016	2015
→	Europe	49%	44%
→	North America	36%	38%
→	Rest of the World	15%	18%

*Average

WHY WORK AT WERFENLIFE?

BECAUSE...

We are...

- One of the top IVD companies worldwide.
- A global leader in Hemostasis, Critical Care and Autoimmunity Diagnostics.
- A technology pioneer with relentless focus on innovation and customer driven R&D.
- A privately owned, growing company.

We have...

- More than 50 years of experience in the fields of Healthcare and Life Sciences.

We offer...

- Multiple career paths and growth opportunities around the world.
- Professional and personal development opportunities through coaching, mentoring and on the job training.

We are committed to...

- Contributing to a healthier society.
- Enhancing the quality of life of people around the world.
- Helping secure the health and well-being of future generations.

The key to the success and growth of WerfenLife has always been and will continue to be **Talent**.

We develop tools and solutions focused on attracting the best talent, we provide learning and development opportunities, as well as career management and talent planning resources.

Our employees have full ownership of their professional development as we understand that, as they learn about their strengths, skills, capabilities and ideas, they will be able to make a greater contribution to the business and, ultimately, for patients and customers around the world. Our employees are highly committed and passionate about their work and their contribution to a healthier world.

LEADERSHIP PROGRAMS AT WERFENLIFE

We offer interesting career opportunities for MBA graduates with a minimum of 3 years’ work experience and a willingness to relocate internationally.

Global Employee Program:

MBA candidates who demonstrate leadership and learning potential, and who aspire to grow internationally, can opt for a global career path that includes 2-3 positions in different locations before reaching their target position.

General Management Development Program:

Top notch MBA candidates are offered a fast track program that will allow them to reach a General Manager position within a certain number of years.



Our 50th Anniversary celebrations around the world.

In constant currency terms, all geographical areas grew in 2016 with reference to 2015

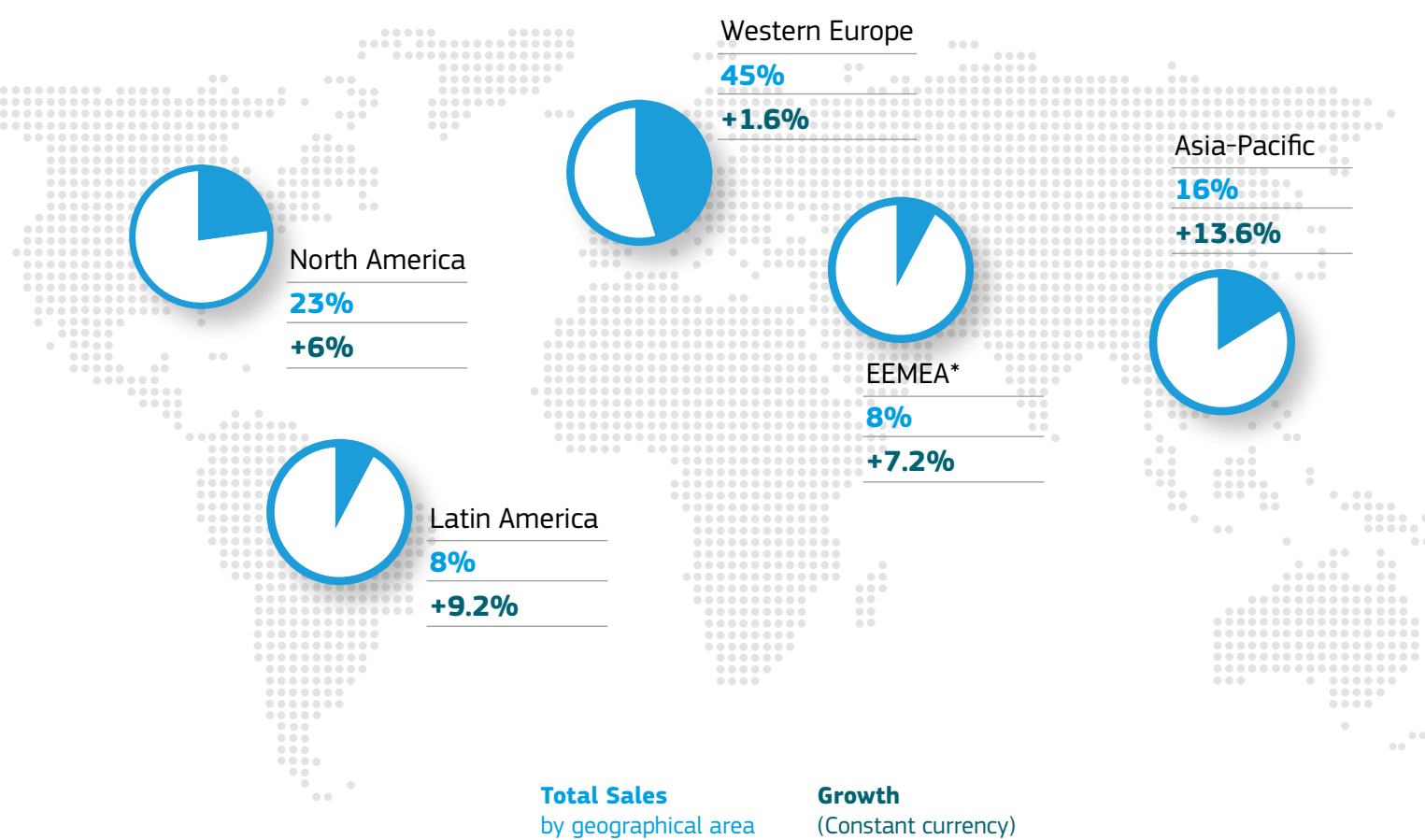
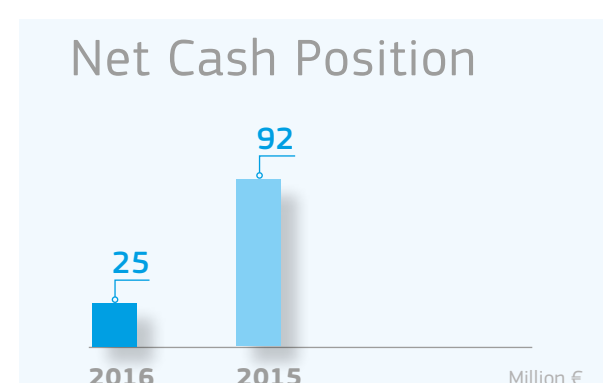
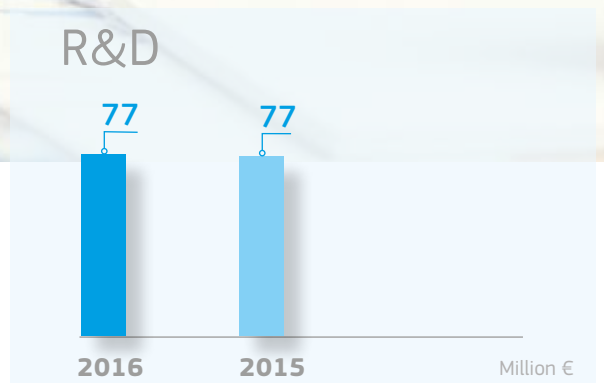
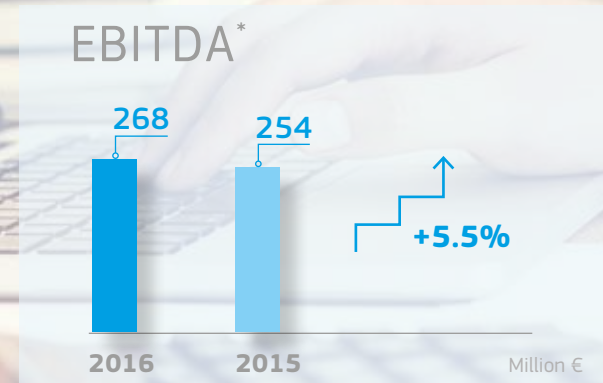
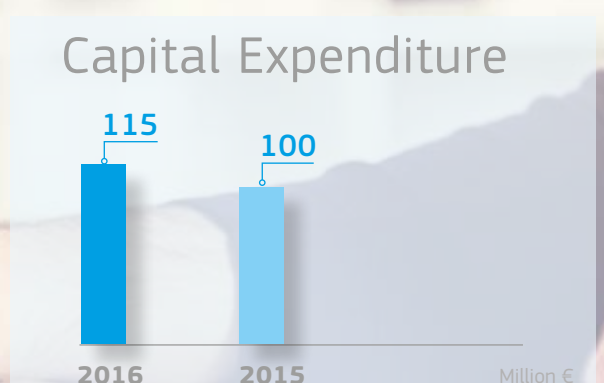
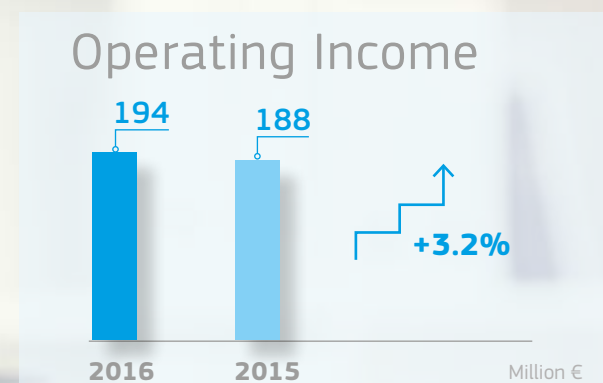
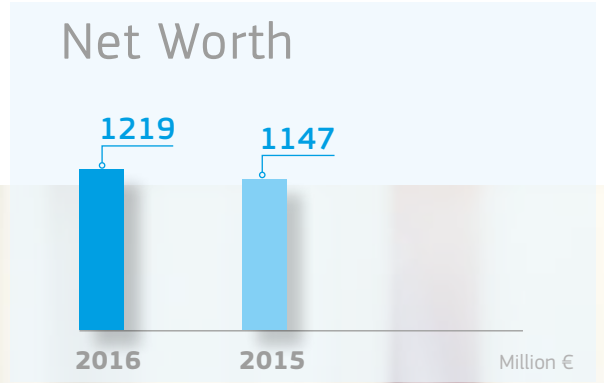
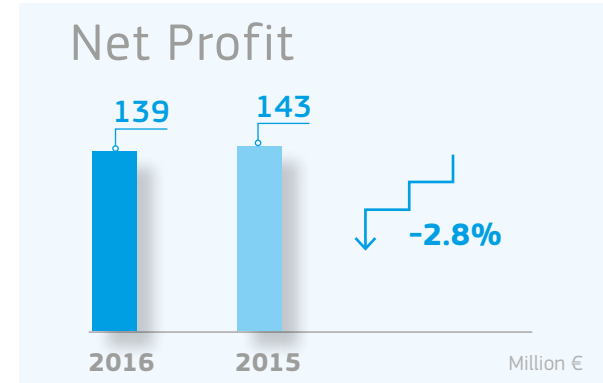
Steady growth in all business divisions and geographical areas.

Sales in 2016 reached **1,193 million euros**, representing a **1.5%** growth over 2015. This result was affected by the depreciation of the Chinese yuan, the pound sterling and the Mexican peso against the euro. In constant currency terms, the growth was **5.1%**.

Million €	2016	2015	Growth (Constant currency)
Werfen -IVD-	999	963	+5.5%
Medical Devices	194*	212	+2.7%
WerfenLife Total Sales	1,193	1,175	+5.1%

Total Sales by Business Division	
Werfen IVD	84%
Medical Devices	16%

* Bolton Medical and ABS Bolton Medical that are no longer part of WerfenLife have been excluded from the result.



In vitro diagnostic (IVD) testing **impacts approximately 65%*** of all medical decisions.

IVD testing is used to support the diagnosis, monitoring and treatment of acute and chronic clinical conditions. Our products are used in hospital and commercial laboratories and at the hospital point-of-care (e.g. Emergency Departments, Intensive Care Units, and Operating Rooms) by healthcare professionals such as laboratorians, pathologists, physicians, perfusionists, respiratory specialists, and nurses.

Every day, **more than 1 million patient samples are tested with IVD systems developed and manufactured by Werfen** companies: Instrumentation Laboratory (Hemostasis, Critical Care, Patient Blood Management and Clinical Chemistry), Inova Diagnostics (Autoimmunity) and Biokit (Original Equipment Manufacturing).

In addition to our own brand solutions, we sell products from well recognized partners in territories such as Iberia, Italy and Mexico.

We know that the quality of the analysis and timely reporting of results impacts the care and treatment of each patient tested. We operate in a highly regulated environment where it is essential to meet or exceed the rigorous quality standards of worldwide regulatory bodies. We develop and manufacture our products for reliability, consistency and quality. Our customers are healthcare providers for whom excellent patient care, patient satisfaction and healthcare cost control are key priorities. We are passionate and committed to helping our customers achieve these objectives.

Werfen –our *in vitro* diagnostics division– represents 84% of the total revenue of WerfenLife. In 2016, IVD sales reached **999 million euros**.

At Werfen, we are dedicated to developing, manufacturing, and distributing IVD systems for hospitals and clinical laboratories. Our product portfolio includes instruments, reagents and software, as well as quality control in specialized areas. Our main areas of focus are: **Hemostasis, Critical Care and Autoimmunity Diagnostics**.

Hemostasis and Critical Care (Instrumentation Laboratory) have a global market share of 28% and 19%, ranking 1st and 3rd worldwide respectively*. Autoimmunity (Inova Diagnostics) is also a worldwide leader, with a global market share of 19%**.

Behind every sample, there is a patient



* Source: European Diagnostic Manufacturers Association, 2016.

Hemostasis

+6.2%

Growth in constant currency



Critical Care

+5.5%

Growth in constant currency



Autoimmunity

+12.5%

Growth in constant currency



*Source: Boston Biomedical Consultants, 2015.
**Internal source.

The most advanced and comprehensive solutions for Hemostasis testing



Hemostasis:

Hemostasis is the balance of the interaction between blood coagulation proteins, platelets and the vessel walls, which maintains blood flow. Disorders or disturbances of any of these factors may result in bleeding or thrombosis, which can be associated with significant clinical adverse events.

Our Hemostasis testing solutions are typically used in hospital and commercial laboratories, providing crucial diagnostic information for pathologies associated with inherited or acquired blood coagulation defects. They are used to diagnose thrombotic ⁽¹⁾ and bleeding disorders, monitor therapeutic effects and assess the hemostatic balance of patients prior and post intervention.

Through Instrumentation Laboratory, we offer the most advanced automation and standardization of pre-analytical, analytical and post-analytical Hemostasis testing processes. Our extensive range of Hemostasis solutions include, among others, the market-leading ACL TOP® Family and ACL TOP® Family 50 Series of analyzers and the comprehensive line of HemosIL® reagents, complemented with a suite of IT solutions: HemoHub™ and ProDx™. HemoCell™ Specialized Lab Automation is designed to further enhance efficiencies and lower turnaround times for high-volume laboratories. Our Hemostasis testing solutions enable healthcare providers to improve quality of care, increase efficiencies and reduce costs.

New Products and Events in 2016

- **The new ACL TOP® Family 50 Series** was successfully launched in North America during the second half of the year.
- **HemoCell™ Specialized Lab Automation**, the world's first laboratory automation solution designed specifically for Hemostasis testing, was launched worldwide.
- **HemosIL® assays:**
Developed by IL:
 - REDIPLAS™, an important addition to our broad portfolio of liquid, ready-to-use assays, was launched worldwide. The new PT reagent ⁽²⁾ reduces potential for human error and improves turnaround times.
 - Apixaban Testing Solution, an automated assay for the measurement of this direct oral anticoagulant ⁽³⁾, was commercialized in the European market.
- **HemoHub™ Intelligent Data Manager V1.3**, an information management solution for Hemostasis laboratories, was also made available in all markets.

- Developed by Biokit:
 - AcuStar® VWF:CB, aiding in the investigation of von Willebrand Disease ⁽⁴⁾ (VWD), was commercialized in Europe and other markets.
 - HIT-Ab ^(PF4-H) assay that detects antibodies associated with Heparin-induced Thrombocytopenia ⁽⁵⁾ (HIT), received FDA 510(k) clearance in the USA and is now available worldwide.

(1) Thrombosis is the formation of a blood clot inside a blood vessel.
 (2) Prothrombin Time (PT) is a test that is performed to screen for bleeding disorders or monitor vitamin K antagonist therapy (e.g. warfarin).
 (3) Anticoagulants reduce or prevent the clotting of blood. Apixaban is a direct oral anticoagulant (DOAC) developed by Pfizer Inc. and Bristol-Myers Squibb Company and is sold under the trademark, Eliquis®. Although monitoring is not required for patients taking DOACs, there are several exceptions where measurement may be beneficial in order to make more informed healthcare decisions.
 (4) von Willebrand disease (VWD) is the most common inherited bleeding disorder. The disease affects up to 1% of the worldwide population.
 (5) Heparin is the most commonly used parenteral anticoagulant. Heparin-induced Thrombocytopenia (HIT) is a severe adverse drug reaction to heparin that causes low platelet counts, and in some cases, blood clots to form.

Key products:



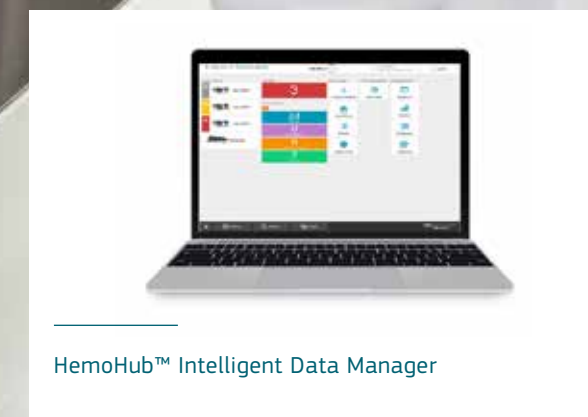
ACL TOP® Family 50 Series Hemostasis Testing Systems



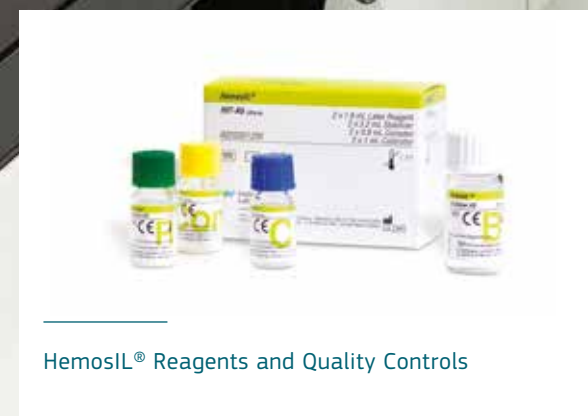
HemoCell™ Specialized Lab Automation



ACL AcuStar® Hemostasis Systems



HemoHub™ Intelligent Data Manager



HemosIL® Reagents and Quality Controls



Critical Care:

Critical Care refers to the specialized management of life-threatening conditions requiring rapid, comprehensive patient care and frequent monitoring -usually in intensive care units, emergency rooms and operating theaters.

Our GEM® Premier™ analyzers measure critical parameters, providing rapid information about the oxygenation status, electrolyte and metabolite levels of critically ill patients. This allows clinicians to take immediate actions, such as controlling ventilation or managing sepsis ⁽¹⁾, acute kidney dysfunction, and other life-threatening conditions.

Our Instrumentation Laboratory solutions are designed to improve the quality of patient care and simplify operations in the laboratory and at point-of-care (ICU ⁽²⁾, CVOR ⁽³⁾, Cath Lab ⁽⁴⁾, ED ⁽⁵⁾ and STAT Lab ⁽⁶⁾) by automating key labor-and skill-intensive tasks, including quality management, system maintenance, and information management. Intelligent Quality Management (iQM®) is the distinctive core attribute of our GEM® Premier™ analyzers that provides real-time error detection, correction and documentation -assuring quality results regardless of testing location or point-of-care operator. The all-in-one, multi-use GEM® PAK offers advanced simplicity. In addition, GEMweb® Plus Custom Connectivity allows complete control by automating quality assurance, enhancing regulatory compliance and reducing staff time.

Key products:

New Products and Events in 2016

- **New GEM® Premier™ 5000 System** with Intelligent Quality Management 2 (iQM®2) was FDA 510(k) cleared in the USA. Representing a true breakthrough in quality management and simplicity, this GEM® Premier™ system enables rapid, quality-assured test results with every sample, reducing error detection time from hours to minutes.

- **New GEMweb® Plus 500 Custom Connectivity** simplifies operator supervision, provides quality management and full traceability, all from a single interface—whether accessed in the lab, at the point-of-care or remotely from an analyzer, PC or tablet.



GEM® Premier™
5000 System



GEM® Premier™
4000 System



GEMweb® Plus Custom
Connectivity

(1) Potential life-threatening complication of an infection.
(2) ICU: Intensive Care Unit.
(3) CVOR: Cardiovascular Operating Room.
(4) Cath Lab: Catheterization Laboratory.
(5) ED: Emergency Department.
(6) STAT Lab: Urgent Test Lab.



Patient Blood Management (PBM):

PBM is a set of clinical, diagnostic and treatment strategies, optimizing medical and surgical patient outcomes by clinically managing and preserving patient blood. PBM is associated with improved patient outcomes, reduction in transfusions, and overall cost of care.

Our ROTEM® analyzers aid in providing rapid, differential diagnosis of coagulopathies in acute care settings, such as Emergency Rooms, Operating Theaters and Intensive Care Units. ROTEM® supports blood transfusion decisions, impacting the use of blood products, patient outcomes and associated costs.

Key products:

New Products and Events in 2016

- **Tem**, with its flagship ROTEM® systems, was acquired by WerfenLife in September 2016.
- **ROTEM® sigma**, a fully automatic testing system that allows whole blood closed-tube sampling without pipetting or manual reagent handling, was introduced in Europe and select international territories. This simplification of testing allows the direct application at point-of-care and improves patient blood management. The system is not yet FDA 510(k) cleared in the USA.



ROTEM® sigma



ROTEM® delta
with ROTEM® Platelet*

*ROTEM® Platelet is not FDA 510(k) cleared.



Autoimmunity:

Autoimmunity refers to problems with the acquired immune system's reactions in which antibodies and immune cells target the body's own healthy tissues by mistake, signaling the body to attack them. Any disease that results from such an aberrant immune response is termed an autoimmune disease (e.g. celiac disease, thyroiditis, rheumatoid arthritis). Autoimmune diseases can affect almost any part of the body, including the heart, brain, nerves, muscles, skin, eyes, joints, lungs, kidneys, glands, the digestive tract and blood vessels. Autoimmune diseases affect approximately 8% of the population, 78% of whom are women, and are one of the top 10 leading causes of death in women under the age of 65.

Through Inova Diagnostics, we are leaders in the development and commercialization of new systems and biomarkers, collaborating with clinical researchers and laboratorians to advance the care of autoimmune disease patients. Our comprehensive product portfolio includes systems and reagents such as the BIO-FLASH® and QUANTA Flash® that support the diagnosis, stratification and monitoring of complex disorders such as the connective tissue disease ⁽¹⁾, rheumatoid arthritis ⁽²⁾, antiphospholipid syndrome ⁽³⁾, vasculitis ⁽⁴⁾ and celiac disease ⁽⁵⁾.

New Products and Events in 2016

- **QUANTA Lite® Calprotectin Extended Range** received USA FDA clearance. The test aids in the diagnosis of Inflammatory Bowel Disease (IBD) ⁽⁶⁾, and can help differentiate IBD from Irritable Bowel Syndrome (IBS) ⁽⁷⁾. QUANTA Lite® Calprotectin Extended Range has a broader analytical measuring range compared with other FDA cleared assays.
- Several tests that aid in the diagnosis of different autoimmune diseases, received USA FDA clearance. Among them, QUANTA Flash® dsDNA for systemic lupus erythematosus ⁽⁸⁾; QUANTA Flash® Jo-1 for idiopathic inflammatory myopathy ⁽⁹⁾ and QUANTA Flash® Scl-70 for systemic sclerosis ⁽¹⁰⁾.
- **QUANTA-Lyser® 4000**, an ultra-high throughput IFA ⁽¹¹⁾ processor, was launched globally. QUANTA-Lyser® 4000 reduces hands-on time, safeguards reagent and sample integrity and accelerates processing speed.
- A semi-exclusive license agreement was signed with Protagen AG for anti-BICD2, a novel autoantibody found in approximately 30% of patients with systemic sclerosis (SSc), and associated with a subform of SSc.

(1) Connective tissue (e.g. bone, fat and cartilage) supports organs and other parts of the body. Connective tissue diseases usually affect joints, skin or muscles, but in some cases also organs and blood vessels.
 (2) Disease causing inflammation in the joints and resulting in painful deformity and immobility.
 (3) Disorder of the immune system that causes an increased risk of blood clots.
 (4) Group of uncommon diseases which result in inflammation of the blood vessels.
 (5) Serious genetic autoimmune disorder where the ingestion of gluten leads to damage in the small intestine.
 (6) An autoimmune disease of the digestive system.
 (7) Less serious, functional disorder of the digestive system.
 (8, 9, 10) Connective tissue diseases.
 (11) Indirect fluorescent antibody (IFA) test is a laboratory technique that uses fluorescent dyes to identify the presence of antibodies that are bound to specific antigens.

Key systems:



NOVA View®
Digital IFA Microscope



BIO-FLASH®
Chemiluminescent Analyzer



QUANTA-Lyser® 4000
IFA Processor



QUANTA Link®
Data Management System

BUSINESS

IN VITRO DIAGNOSTICS OEM PRODUCTS & SERVICES

Original Equipment Manufacturing (OEM):

Offering products and services to other IVD companies.

Our Biokit OEM immunoassays and biomaterials ⁽¹⁾ solutions consist of Proprietary Products and Custom Development & Manufacturing Services. Our knowledge and expertise is mainly in IVD markers based on antigen-antibody reactions in the fields of infectious diseases, serum proteins, TDMs ⁽²⁾, hormones and vitamins, among others.

Our proprietary assays offer IVD solutions for the screening and diagnosis of several infectious diseases (e.g. hepatitis, retrovirus ⁽³⁾, and TORCH syndrome ⁽⁴⁾) and for the clinical determination of serum proteins, among other applications. We sell these products either with proprietary label, private label or in bulk format.

We also offer a broad range of proprietary biomaterials, including antibodies, antigens and sera validated for use in IVD applications.

Regarding custom development and manufacturing, immunoassay is our core competence. Using our expertise, we offer long-term partnerships to our OEM customers, bringing end-to-end assay lifecycle capacities under a single roof. Over 80 companies in the IVD industry source immunoassays and biomaterials from Biokit. 6 out of the top-ten IVD manufacturers are our customers and we are consistently rated as a top-quality supplier by them. In addition, these capabilities and solutions are used by other Werfen IVD companies in the Hemostasis and Autoimmunity areas.

(1) Biomaterials are any substances of biological origin (usually proteins) that have been designed, produced and purified to function as the main raw material on an IVD test.

(2) Therapeutic Drug Monitoring.

(3) A family of viruses that includes HIV and HTLV.

(4) Infection of a developing fetus or a newborn baby. TORCH = Toxoplasmosis + Rubella + Cytomegalovirus + Herpes Simplex.

(5) Chemiluminiscent ImmunoAssays (CLIA) are based on the Antigen (Ag) - Antibody (Ab) reaction where the reaction detection is done by chemiluminescence (the production of light from a chemical reaction, generally within the visible spectra).

(6) An analytical immunoassay technique used to measure the concentrations of proteins (and other analytes) in serum in clinical chemistry instruments.

(7) An analytical immunoassay technique used in serology to differentiate and confirm the antibodies of a sample to the different antigens of a virus, bacteria or parasite.

Over 80 companies in the IVD industry rely on our biomaterials and other OEM services



New Products and Events in 2016

Assays

- HemosIL® AcuStar® vWF Collagen Binding CLIA assay ⁽⁵⁾ developed for Instrumentation Laboratory
- BIO-FLASH® HIV Ag/Ab, HTLV Ab, HBe Ag, anti-HBe, VZV IgG and VZV IgM CLIA assays
- Two CLIA assays for OEM customers
- QUANTILab CRP ultrasensitive turbidimetric assay ⁽⁶⁾ developed for Instrumentation Laboratory

Biomaterials

- Recombinant antigens produced with IBES technology for Herpes 1 and Herpes 2
- Parvovirus B19 antigen
- anti-HBe monoclonal antibodies
- FITC conjugates developed for Inova Diagnostics

Analyzers

- **AutoScan PRO**, a platform for automated interpretation of Western blot assays ⁽⁷⁾, was launched.

Others

- Achieved exclusive distribution agreement of the BIO-FLASH® system for the IVD panel of infectious diseases with Shanghai Kehua Bio-Engineering co., Ltd. in the Chinese territory.



Assays



Biomaterials



Biokit Laboratory



New Tarancón Logistics Center in Spain

Our solutions help enhance the recovery time and comfort of patients

BUSINESS

MEDICAL DEVICES

The Medical Devices division represents **16%** of the revenue of WerfenLife. In 2016, total sales reached 194 million euros.

Medical Devices grew **2.7%** with reference to 2015.

Medical devices that range from disposables such as gloves to complex machines like microscopes or x-ray machines, are designed to help diagnose, monitor, and treat different diseases and conditions.

We manufacture our own brand of medical devices (Leventon), primarily infusion systems, and act as distributors of both own and third-party medical devices as well as third-party scientific instrumentation ⁽¹⁾.

Technology for life



(1) Scientific instruments are products used in scientific research, examples include measuring instruments and quality controls.

BUSINESS

MEDICAL DEVICES INFUSION SYSTEMS



We specialize in Infusion Systems and manufacture medical devices such as the DOSI-FUSER®, a single-use, continuous-infusion system for ambulatory patients and DOSI-FLOW®, a single use intravenous (IV) flow regulator. In addition, we manufacture Respiratory Care Products such as the SPIRO-BALL® and TRI-BALL® - volumetric exercisers that help patients breathe normally after surgeries and thus accelerate their recovery time.

MEDICAL DEVICES DISTRIBUTION OF MEDICAL DEVICES AND SCIENTIFIC INSTRUMENTATION

We distribute a large variety of our own and third-party medical devices and scientific instrumentation such as disposables, products for interventional cardiology, orthopedic implants, surgical instruments and life sciences equipment.

The distribution of medical devices is carried out by our affiliates in Europe: Izasa Hospital in Spain, Medicinália Comédica in Portugal, Nicolai in Germany, and Comesa in Austria, Germany, and Poland. In addition, we cover the distribution of scientific instrumentation in the Iberian Peninsula through Izasa Scientific.

Key products:

New Products and Events in 2016

- Reached a leadership position with **DOSI-FUSER®** in USA, Portugal and France.
- **DOSI-FUSER® High Volume** launched successfully and made us the manufacturer with the widest range of elastomeric pumps.
- A project financed by the European Space Agency (ESA) chose **DOSI-FUSER®** as the pumping system for their ammonium micro analyzer used to monitor water treatment processes. It will be utilized at the **International Space Station (ISS)**.



DOSI-FUSER®



TRI-BALL®



SPIRO-BALL®



DOSI-FLOW®



Disposables



Interventional Cardiology



Orthopedics



Surgical Equipment



Scientific Instrumentation

Milestones

Integration of the Tem and Accriva organizations, product portfolios, strategies and processes

Both companies were acquired in Q4 2016 and early 2017, respectively. Their product portfolios include ROTEM® testing systems, for patient blood management, Hemochron®, the gold standard for Activated Clotting Time ⁽¹⁾ (ACT) testing, and VerifyNow®, the leading system for platelet function analysis ⁽²⁾. Their addition to our existing Critical Care and Hemostasis product portfolio creates an even more comprehensive and integrated testing solution for hospital acute care settings and laboratories.

Final move to the new Biokit facilities

The new site of approximately 25,000m² represents an investment of 55 million euros and will host almost 400 employees in Barcelona, Spain.

Building new facilities for Leventon

New industrial center of 10,000 m² in Sant Esteve Sesrovires (Barcelona, Spain).

(1) The ACT test measures the time it takes a blood clot to form.
 (2) Platelet function testing is done to evaluate the inhibition of platelet function to certain medication.

Anticipated Products Launches

HEMOSTASIS

IT Solutions

- HemoHub™ Intelligent Data Manager: full release of a new version that fully integrates HemoCell™ Lab Automation
- ProDx™ Remote Support Suite: implementation in most key territories. Connecting customer's ACL TOP® Hemostasis Testing Systems to technical customer support team dashboards enabling targeted actions and increasing customer satisfaction and efficiencies.

HemosIL®

- Launch of HIT-Ab ^(PF4-H) in the USA
- Anti-β2 Glycoprotein-I Domain 1 assay for antiphospholipid syndrome (APS), is planned to launch in early 2017.

CRITICAL CARE

- GEM® Premier™ 5000 System and GEMweb® Plus 500 Custom Connectivity: our new critical care analyzer and Custom Connectivity solution are planned to go into full commercial release in Europe and in USA during 2017.

AUTOIMMUNITY

- Several new QUANTA-Flash® assays for BIO-FLASH® are planned to launch with CE mark in 2017.
- QUANTA-Lyser® 3000, a high throughput EIA/IFA processor, is planned to launch globally. Similar to QUANTA-Lyser® 4000, the instrument reduces hands-on time, safeguards reagent and sample integrity and accelerates processing speed.



PhotoLife contest was organized to celebrate the 50th Anniversary of WerfenLife.

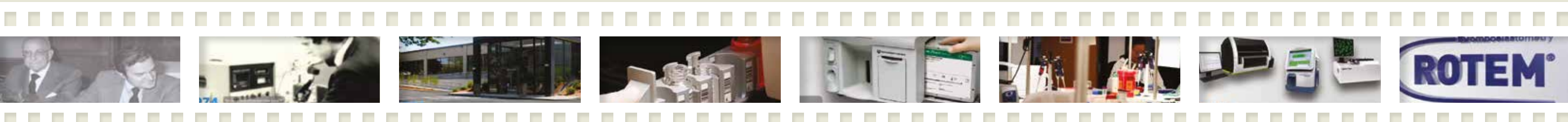
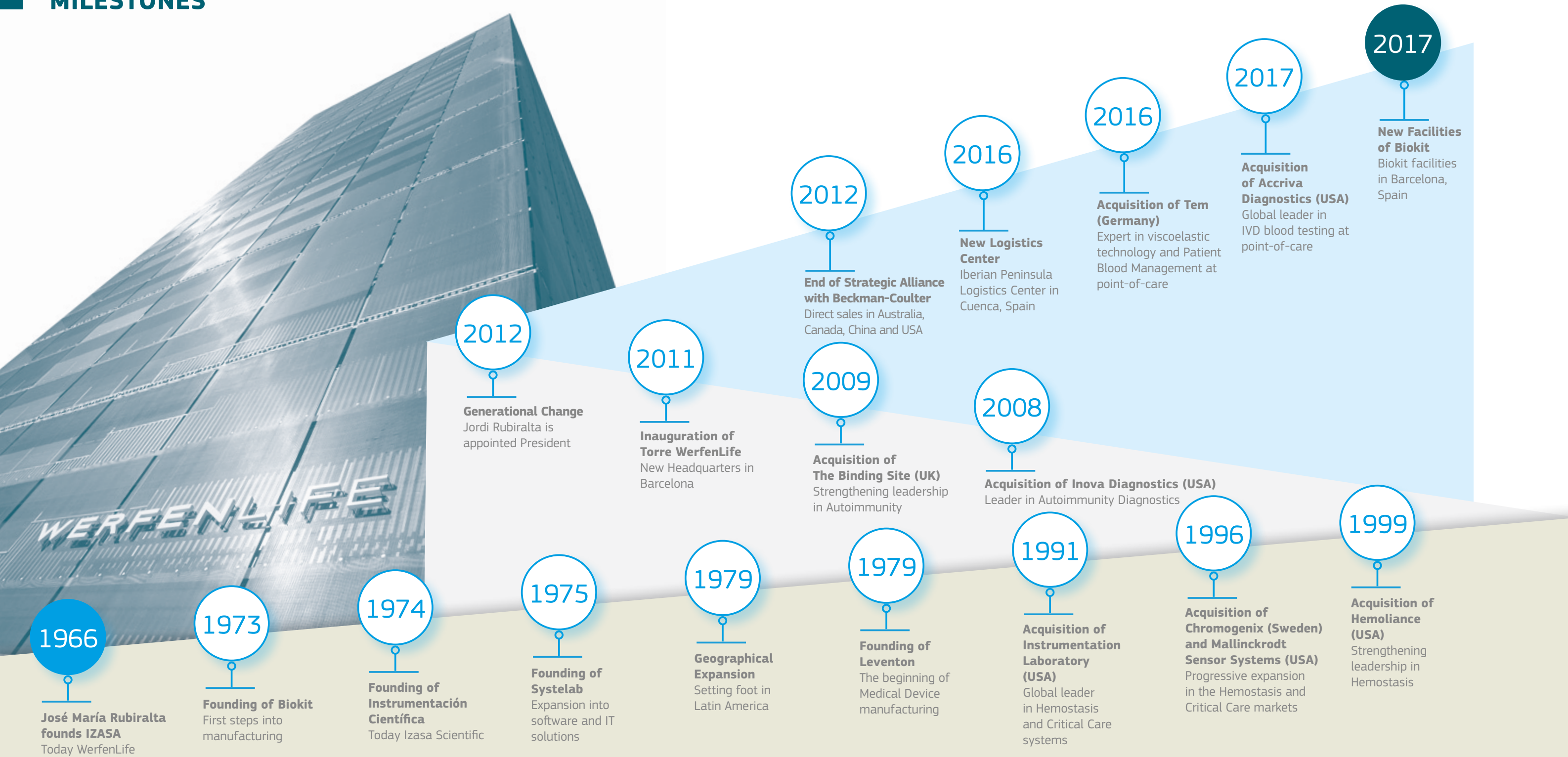
Here is a collection of pictures taken by our employees around the world.



New facilities of Biokit in Barcelona, Spain



MILESTONES



WERFENLIFE 50^{years}
GROWING TOGETHER

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