

Annual Report 2018

ON TRACK

**“PROGRESS IN SCIENCE DEPENDS
ON NEW TECHNIQUES, NEW
DISCOVERIES AND NEW IDEAS,
PROBABLY IN THAT ORDER.”**

Sydney Brenner, Nobel prize-winning pioneer of molecular biology

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Dear Clients and Partners

Dear Employees

Dear Shareholders

Dear Stakeholders

The life sciences are fascinating, not least because they deal with life itself. Every new finding directly affects each and every one of us. In recent years, numerous developments in methods and technologies have led to enormous gains in our understanding and knowledge. In many cases, automation sets the pace. For example, genome sequencing is now affordable and available to almost every laboratory, thanks to next-generation sequencing platforms. The parallel analysis of many genomes now enables, for example, population genetics to reveal surprising relationships in the interplay between various organisms.

These new methods and technologies not only improve our understanding of biological processes, but thanks to the CRISPR/CAS9 method, now also enable precise modification of organisms without introducing additional 'foreign' genes. In plant breeding, for example, the defense mechanisms of crops can be bolstered, meaning that plant protection products are no longer needed. Similarly, curing diseases that were previously almost untreatable, such as cystic fibrosis or muscular dystrophy, is now a step closer to becoming reality.

These scientific advances and breakthroughs make up the environment in which HSE AG (Hombrechtikon Systems Engineering AG) is active. We work closely with our clients to develop systems and technologies that advance life sciences. Our strategy is to understand end users and their work and then translate this understanding into technology developments for our clients. Thanks to our understanding of reality in the lab, we can engage in constructive dialog with our clients to find the best possible solutions and avoid unnecessary learning curves.

Business development

In 2018, HSE was able to seamlessly continue the success of its first financial year. Turnover increased by 8.5% to around CHF 8.7 million. The main reason for this was new client business, which has grown by an impressive 160%. Client relationships established in 2017 were also further consolidated and additional clients were acquired. An extraordinary increase in net profit was achieved, representing more than 300%. Thanks to ongoing cost optimization measures, this increased to CHF 558,056.

Our largest client continues to be the QIAGEN Group, with a stable sales volume of CHF 6.6 million. The service contract concluded with our former parent company secured our sales base in the second financial year once again. Nevertheless, our dependence on QIAGEN has already been reduced due to strong growth from new clients.

Creating a one-stop-shop offering

Significant investments were made in sales and marketing activities in 2018. These will lead to further growth in the new client segment in the coming years, in conjunction with the broad network accessible to the HSE team.

In particular, there is great potential in the newly created one-stop-shop offering, which arose in response to specific client needs. As well as the development, HSE also handles the entire technical product management for the client and coordinates the manufacture of instruments with international contract manufacturers. This allows the client to pass on the full complexity of product life cycle management to HSE so that they can focus on their core competencies. This in turn reduces business risk, decreases costs and accelerates market launch.

Key directions in research and development

To optimize costs, timelines and risk for its clients, HSE also continually develops modules and technologies that can be used flexibly in client developments. We are pleased to report that the company was awarded a Eurostar grant in 2018 for one of these innovations.

An OEM agreement allows specific use of QIAGEN instruments and reagent technologies, as well as product platforms in client projects. Based on these technologies, HSE has established a partnership that will provide access to the rapidly growing proteomics market. A new OEM product for protein purification is scheduled for market launch in mid-2019.

OUR VALUES – OUR DNA

HSE is built on six core values that are shared by all our colleagues. They are our DNA, playing a key role in defining our performance as individuals and as an organisation.

Enjoyment: We work on projects that interest us, with people with whom we enjoy working.

Usefulness: The projects we engage in should benefit our clients, our colleagues and society. We continually improve ourselves as individuals and as a company.

Ambition: We strive for excellence and continually push our boundaries to build something bigger than ourselves. This is the source of our satisfaction.

Grounded in reality: We make well-considered, disciplined and fact-based decisions. In doing so, we confront the hard realities, draw appropriate conclusions and focus on the best possible implementation. Pressure from tight deadlines must not affect the quality of our work.

Seeking out the best solution: We are curious and open-minded, guided by truth and transparency. We encourage and seek feedback in order to learn rapidly.

Fairness and respect: We treat everyone fairly and with respect. We communicate openly and honestly. This forms the basis for respectful and mutually challenging discussions.

Employee development

Employees are the key success factor at HSE. The open and transparent communication culture, participatory leadership, modern infrastructure and dynamic market environment with attractive projects enable the company to retain highly qualified employees and to gain new, excellent talent. With the Employee Engagement Platform introduced at the end of 2018, employees now have another opportunity to get involved in shaping the way they do their work and identifying potential for improvement. Employees also greatly appreciate the flexible working hours and part-time options as well as being able to work from home.

Looking ahead

Life sciences research at universities and research institutes, pharmaceutical research and medical diagnostics have been regularly growing by 5 to 6% per year for many years. The current global market volume is equivalent to around CHF 110 billion, according to the European Observatory on Health Systems and Policies. HSE expects the market to continue to expand over the coming years. With the world's population continually growing and ageing and new diagnostic and therapeutic options continually becoming available, this assures a stable long-term environment with little economic fluctuation.

This also means that the need for engineering and development expertise will continue to increase in all areas of the life science industry. German-speaking countries and Western Europe as a whole have many major corporations, hidden champions and a large number of start-ups in the life sciences and diagnostics fields. Because of this, HSE will remain regionally focused, with its base in Switzerland. With extensive experience in international projects, we can also provide expert support to our international clients in the US and Asia.

The Board of Directors and management team see a positive future, following on from a successful second financial year. We are very mindful that without you – our clients and shareholders – we would never have come this far. We would like to pass on our sincere thanks for your trust in us. We would also like to thank our employees and colleagues for their continued commitment to the success of HSE and our clients, through their ideas, passion and outstanding commitment to their work.

Hans Noser

Dr Michael Collasius



Chairman of the Board

Chief Executive Officer

“The need to comply with regulatory requirements in our projects and internal processes is a fundamental part of our culture at HSE. Being responsible for proper implementation of the necessary requirements in this environment is a real pleasure for me.”

Pit Muggli, Quality & RA Manager
HSE AG

VISION

We help our clients achieve their next scientific breakthrough.

MISSION

By combining our application and engineering expertise, we aim to develop superior tools that enable our clients to understand the key principles of life.

In doing so, we implement systems and processes that meet the precise needs of our clients.

PROMISES

1 We focus all of our energy not only on meeting our clients' expectations, but also on exceeding them whenever possible. We aim to ensure they receive the greatest possible added value and the best possible quality.

2 The consistent application of our clearly defined processes and the uncompromising implementation of all requirements of our clients and regulators ensure the safety and performance of our products and services.

3 All of our employees at all levels are required to comply with all applicable specifications of our clients and the authorities and to ensure effective quality management at all times. We want to make a clear difference for our clients through our high-quality services.

4 To continue to boost our performance, we embrace continual improvement methodologies in compliance with regulatory requirements. We set objectives for the systematic management of these processes and review them regularly.

Support throughout the entire product life cycle

The ETH spin-off, rqmicro, has developed an innovative method for quantitative detection of pathogens in drinking water in just a few hours. The scientists have not only placed their trust in the development and industrialization experience of HSE engineers to turn the technology into a marketable product. The one-stop-shop solution also includes responsibility for instrument production and support.

Clean water is essential for humans and the environment. The ETH spin-off, rqmicro, (rapid quantitative microbiology) has developed a novel method that can significantly improve the safety of drinking and industrial water. Using a biological sensor system, microbial pathogens such as Legionella bacteria, which live in water and can cause dangerous Legionnaire's disease, can be detected and quantified much faster and more easily than was previously

possible. The results are available after just one to two hours instead of after more than ten days with conventional standard methods.

Support for rapid development and market launch

The tremendous potential of the rqmicro method was also recognized by the European Commission. It provided the start-up company with EUR 2.2 million under the SME Instrument to accelerate the development and market launch of the products. rqmicro beat off competition from 1,200 competitors in the selection process.

The microbiologists obtained support from HSE so that the funding could be used effectively and marketable products launched as quickly as possible. As part of a one-stop-shop solution, the development service provider has not only assumed responsibility for the industrialization of the systems, but also for production and support of the instruments over their entire life cycle.

Multiple technologies combined into one system

The rqmicro method combines various technologies such as immunomagnetic separation, flow cytometry and microfluidics. The pathogens are detected by specific antibody-coated magnetic particles and can then be isolated from the sample by means of magnetic separation in a microfluidic system. The bacteria, tagged additionally with a second fluorescent antibody, are quantified in a flow cytometer and rapidly counted. Alternatively, other analytical methods such as PCR or fluorescence microscopy can be used for the measurement.

“OUR PARTNER NETWORKS THAT WE HAVE BUILT UP OVER THE YEARS FORM THE FOUNDATION OF OUR ONE-STOP-SHOP. THEY ENABLE US TO DEVELOP SOLUTIONS RAPIDLY AND COMPREHENSIVELY IN CLOSE COLLABORATION WITH OUR CLIENTS, TO PRODUCE THE INSTRUMENTS COSTEFFECTIVELY AND TO RELIABLY SUPPORT THEM OVER THE ENTIRE LIFE CYCLE.”

Patrick Widler, Chief Commercial Officer HSE AG



“THE ONE-STOP-SHOP COOPERATION WITH HSE ALLOWS US TO FOCUS OUR RESOURCES ON FURTHER DEVELOPMENT OF OUR TECHNOLOGIES AND COMMERCIALIZATION OF OUR PRODUCTS. AT THE SAME TIME, IT INCREASES THE RELIABILITY OF OUR SYSTEMS IN TERMS OF AVAILABILITY AND LIFE CYCLE MANAGEMENT.”

Dr. Hans Anton Keserue, CEO rqmicro

Overcome challenges with a partnership

When it came to transforming this innovative method into marketable products, rqmicro faced challenges typical of smaller and mid-sized biotech companies. These usually lack the personnel resources and specific know-how to master all process steps themselves, which are required from conception through to the development phase, from the production of prototypes through to series production of the product and, finally, to facilitate maintenance and service. The continuously increasing legal and regulatory requirements for laboratory and medical products that need to be met are added on top of this.

With HSE, rqmicro has found a partner whose core competencies include exactly these skills. The development services company, which specializes in life science and diagnostic systems, not only has many years of experience in the engineering of complex instruments based on biological methods. As a former department of the QIAGEN Group, the HSE team was also responsible for the entire life cycle of the products and, therefore, is proficient in setting up and managing production supply chains through to service organizations.

Cost-effectiveness and scalability right from the start

The course that is important for the later production and efficient global service of the instruments is already set at the start. The concept and selection of technologies during the development and industrialization phase greatly influence the later manufacturing costs and also options for production scaling,

if needed. This is even more important if, as in the case of rqmicro, a modular system needs to be built that can be flexibly adapted to the measurement requirements of different organisms and application scenarios. Thanks to the many years of experience in device life cycle management, HSE specialists know exactly which technologies can lead to problems with scaling and subsequent customization, and which are optimal for the needs of rqmicro.

Through HSE, rqmicro now has access to a global production partner network. In this case, small series can be produced close to the site and, with high growth rates, production can be transferred to attractive locations abroad (USA, Asia, Eastern Europe) at the best possible total cost of ownership (TCO). Exclusive cooperation agreements with national and international production partners enable long-term delivery of series in the best possible quality and with attractive terms. Innovations and new technologies from the supplier network flow directly into product development.

From product optimization through to life cycle management

Another strength of the one-stop-shop solution is the support of the product over its entire life cycle. A team of product life cycle managers takes care of all product-related issues such as handling of changes and optimizations. The HSE team also ensures compliance with all standards and regulations. In addition to this, there is a tailor-made, global service concept including the management of spare parts. A proven partner network ensures high-quality maintenance and support services.



S2 LABORATORY FOR TESTING UNDER REALISTIC CONDITIONS

Efficient functioning of laboratory and diagnostic systems needs more than a sophisticated design. This design must also interact optimally with the software, consumables and applications with real samples. To ensure this, laboratory tests under realistic conditions are required many times over, from the first functional model. HSE has a fully equipped and certified S2 laboratory, in which work with critical pathogens can also be carried out.

The results of each development phase, from individual process adaptation to series production, can be regularly checked and optimized in the laboratory using the right sample material and real reagents. These tests also enable HSE employees to give the client immediate feedback from the user's perspective right from the start. This means usability issues can be addressed at a very early stage and the cost of knowledge transfer remains minimal.



“THE RAPID, RELIABLE AND AUTOMATED TESTS FROM RQMICRO SET A NEW STANDARD FOR PATHOGEN DETECTION IN THE FOOD AND DRINKING WATER INDUSTRIES AND IN QUALITY MONITORING. THE HIGH SENSITIVITY AND SELECTIVITY HELP TO IMPLEMENT TARGETED MEASURES.”

Marcel Lüscher, Drinking Water Hygiene Expert, CEO innovation consulting

Therefore, the one-stop-shop solution covers all phases from development to the end-of-life of the product. Thus, rqmicro can focus entirely on its own core competencies in the further development of methods and their commercialization. The cut-

ting-edge technology of the start-up is already being successfully used by many clients, from hospitals and hotels to water laboratories and research institutes. The course is set for further growth – not least because of the partnership with HSE.



“After studying mechanical engineering, I was looking for an interesting challenge in the life sciences field – and I found it at HSE. Here, I can fully contribute my expertise in the development of instruments and key technologies of the future.”

Michael Kühni, Associate
Mechanical Engineer HSE AG



Full speed after just two years – and with 500 years of experience

In its first two years, HSE AG has already achieved many milestones. The reason why this young company has been able to move into new areas so quickly is the key role played by the HSE team in the development of technology for genome sequencing from day one. In fact, staff members with a combined total of 500 years of experience work at HSE in Hombrechtikon on laboratory automation of the future.

The first sequencing of an entire human genome, which began in 1990, required millions of individual experiments and analyses and took over ten years to complete. The workload involved needed to be massively decreased to open up a wide range of applications for genome sequencing. The absolute necessity of automating particularly time-consuming process steps is at the origin of today's HSE team.

The first plasmid purification robot

One of the most serious bottlenecks at that time was sample preparation, and the extraction of

plasmid DNA in particular. As part of the QIAGEN Group, the Automation team launched the world's first microtiter plate-based nucleic acid purification robot in 1996, which greatly facilitated the decoding of the first human genome. Inspired by this success, the Automation team developed a complete portfolio of systems for different sample throughputs and volumes. This includes the unique QIAcube, which fully automates the DNA extraction process without changing the usual manual procedure.

Following this breakthrough, further components were developed along the process chain with the

aim of eliminating time-consuming manual steps from the process, from sample to result. This made molecular biology methods accessible to more and more researchers and application areas outside of the original scientific fields.

Integrated system enables a wide range of applications

Findings and methods from the 2000s onwards were increasingly used in practical applications in molecular diagnostics. In the initial phase, however, the complex procedures could only be carried out by highly specialist teams, which severely restricted their use. It was only with the development of

integrated systems such as the QIA Symphony that it became possible to use molecular diagnostics in small and less specialised labs. The QIA Symphony, developed by the HSE team, is one of the most successful DNA processing systems available, with more than 2,000 units installed.

The team achieved another milestone with the development of a next-generation sequencing system. Once again, this automated the individual process steps of a highly complex analysis process. With the integration of bioinformatics, the results of patient sample analyses now have a medical context. This enables clinicians to make better and safer treatment decisions.

Rapid achievement of ISO certification

In just two years, and with more than two decades of experience, HSE has established itself as an independent company in the international market for the development of laboratory automation, analysis and diagnostic systems. It was already awarded ISO 13485 certification under the latest guidelines in 2017, proving its expertise in the regulated IVD market. Conformity of its products in

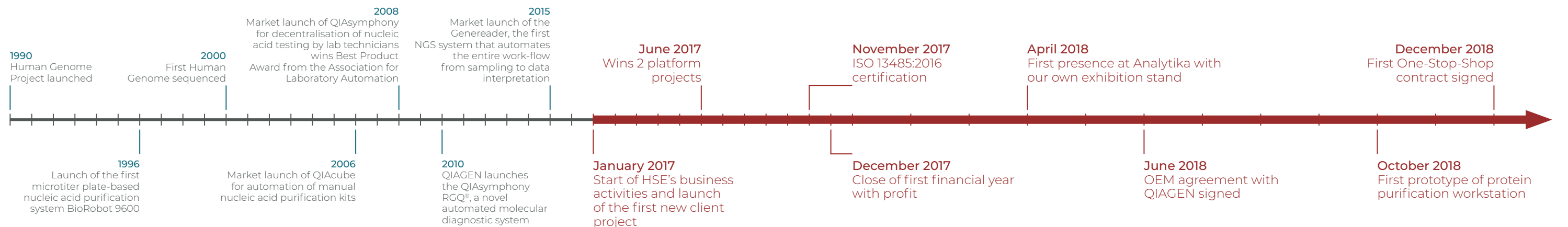
the European (CE-IVD), US (US-FDA) and Chinese (NMPA, formerly cFDA) markets was secured for several of its new clients.

The OEM agreement signed with the QIAGEN Group in 2018 ensures a broad base of technology and method modules. This means that HSE has access to many of the company's technologies. For example, a novel protein purification system for mass spectrometry was developed for a client in the up-and-coming field of proteomics, based on these platform technologies. This system will be launched mid-2019. In 2018, the prototype for a protein purification workstation was successfully tested. Technologies and products for automated sample preparation for genome analysis are among the many other projects that HSE is currently developing for clients in a wide range of life science sectors. These will be launched in 2019.

One-stop-shop solution and a focus on the future

The innovative one-stop-shop solution promises great potential for the future. The first contract for this new approach was signed in 2018. With it, HSE not only assumes responsibility for the development and industrialisation of

instruments, but also for their production and support over the entire product life cycle. This allows clients to focus on their core competencies in the further development and commercialization of their technologies. For its part, HSE AG will continue to focus fully on translating its clients' ideas and visions into ground-breaking and economically successful innovations.



Combining engineering and biology into marketable solutions

Instrument development is a methodical and continual learning process for Konstantin Lutze. Two factors are crucial in this for the HSE CTO. Firstly, in addition to their expertise, engineers must also have a deep understanding of biological processes. Only when both sides understand each other can productive dialog develop. Secondly, project managers need to find the right combination of structured coordination and personal responsibility. To facilitate this, HSE has adapted agile methods to the specific needs of laboratory automation.

Mr. Lutze, life sciences and engineering are two very different disciplines. How can their different approaches be reconciled for the development of automated solutions?

It is absolutely true that biologists and engineers approach problems in very different ways. While biologists try to delve into the complexity of nature as deeply as possible, one layer at a time, engineers build their developments from the bottom up, based on the laws of physics. For example, biologists know that a certain step requires a temperature of 60° Celsius. However, for their design, engineers are more interested in whether an accuracy of one degree is sufficient or whether the temperature must be accurate to a tenth of a degree. Mutual understanding is very important to reconcile these two ways of thinking and proceeding. Engineers must be as interested in the biological processes as biologists are in the technological parameters. At HSE, we have people who build bridges on both sides – system engineers who have

worked in biology and system analysts with background in chemistry or biology who have studied engineering.

How does this mutual understanding pay off in the projects?

Let's take a typical example from the lab. For a human experimenter, decanting a liquid supernatant is a simple, everyday procedure. But from the perspective of an engineer, this step is extremely complex. It is almost impossible to reproducibly automate it. To avoid this, biologists and engineers need to work together to create a different process workflow. This requires close communication, which is only possible if there is mutual technical understanding and mutual appreciation.

In which project phases is this mutual understanding most important?

It is an important success factor in all phases, because development projects are always a joint learning process. The key factor

for success, however, is a mutual technical understanding, especially at the very beginning. If the engineers in the lab "look over the shoulders" of biologists and chemists to understand the entire process, they need to be able to have a say. If they ask specific questions and understand why individual steps are carried out in that particular way, this phase can result in simplifications that considerably increase the efficiency of the system.

Laboratory systems usually combine many different technologies. How can the project management help to ensure that all disciplines work together optimally?

What is known as concurrent engineering is probably the biggest challenge in development projects. We have continually optimized our approach over the last 20 years. We now base this on agile methodology, which we have derived from software engineering and adapted to the specific needs of instrument development. In essence, it's about creating viable

versions as quickly as possible, which are then completed and improved in iterations as we move towards the design objective.

Iteration cycles of one to two weeks are common in software development. Is this kind of interval realistic in instrument development?

A timeframe of one to two weeks doesn't work in an environment where components not only need to be designed, but also procured or even specially produced. We work in four-week iterations. Even this may seem to be too fast a tempo because many processes take longer. This is where our experience comes into play. You need to define the work packages appropriately. Whenever possible, we perform partial mini-integrations per iteration of implemented functionality – and learn! Longer tasks we break down to

fit to the iteration heart-beat. For example, the iteration objective could be that all subsystem components are drawn and ordered and chemistry has to decide on certain compounds.

What are the benefits of monthly mini-integrations?

Firstly, design errors become visible very early on, which means that less work is needed to correct them. Secondly, we can quickly determine why an objective has not been reached and take any steps that are needed. We always notice a big difference when we bring together the results of the various teams after four to six months in a major integration phase. This is precisely the phase when most projects exceed their timelines. Instead of just two weeks, as in successful agile projects, it often takes several months to combine the com-

ponents, because many areas need to be improved. If the system is only integrated in a half-yearly cycle, then all of the difficulties remain in the dark for six months.

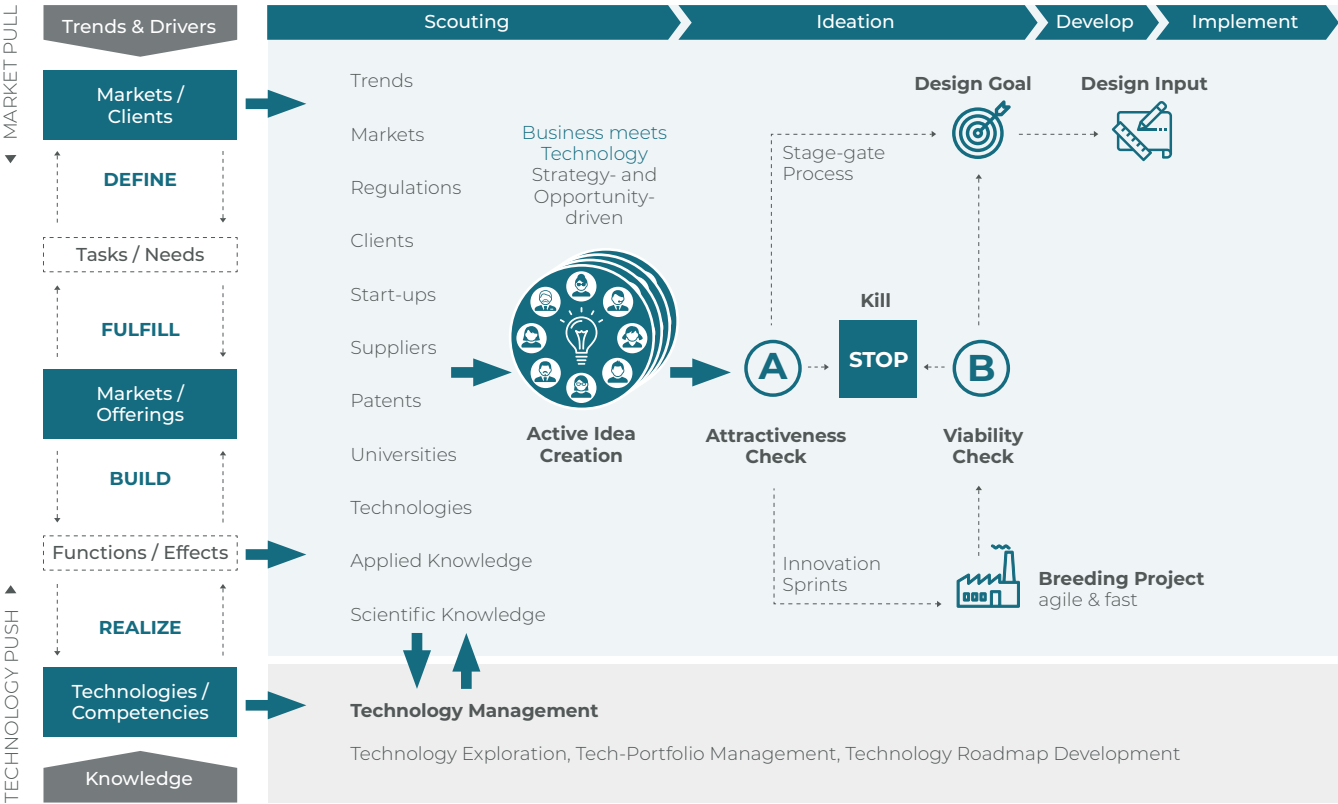
How do your agile methods impact collaboration within and between teams?

Firstly, an agile approach gives each individual responsibility for their work packages, in which they define the objectives. Secondly, the team as a whole always has a certain duty. It is only when everyone supports each other that the common objectives can be achieved. Taking an iterative approach means you're following a common, methodical and continual learning process. And that essentially defines a development project. On our way to developing a new instrument, we frequently find ourselves in unknown terrain. The methodology enables us to coordinate the learning processes of all stakeholders and use the synergies of our know-how in the best possible way. Last but not least, this is also beneficial for the motivation of each individual in the team.

To what extent does your agile methodology increase motivation?

Sprint review meetings take place, for example. In the meetings, we don't just show what didn't work – there's a strong focus on what has been successfully implemented. This means everyone sees the ongoing progress. If someone is facing a difficult challenge, they are not alone and can rely on the support and experience of others. This also means that not only technical challenges are handled in a

INNOVATION PROCESS AT HSE

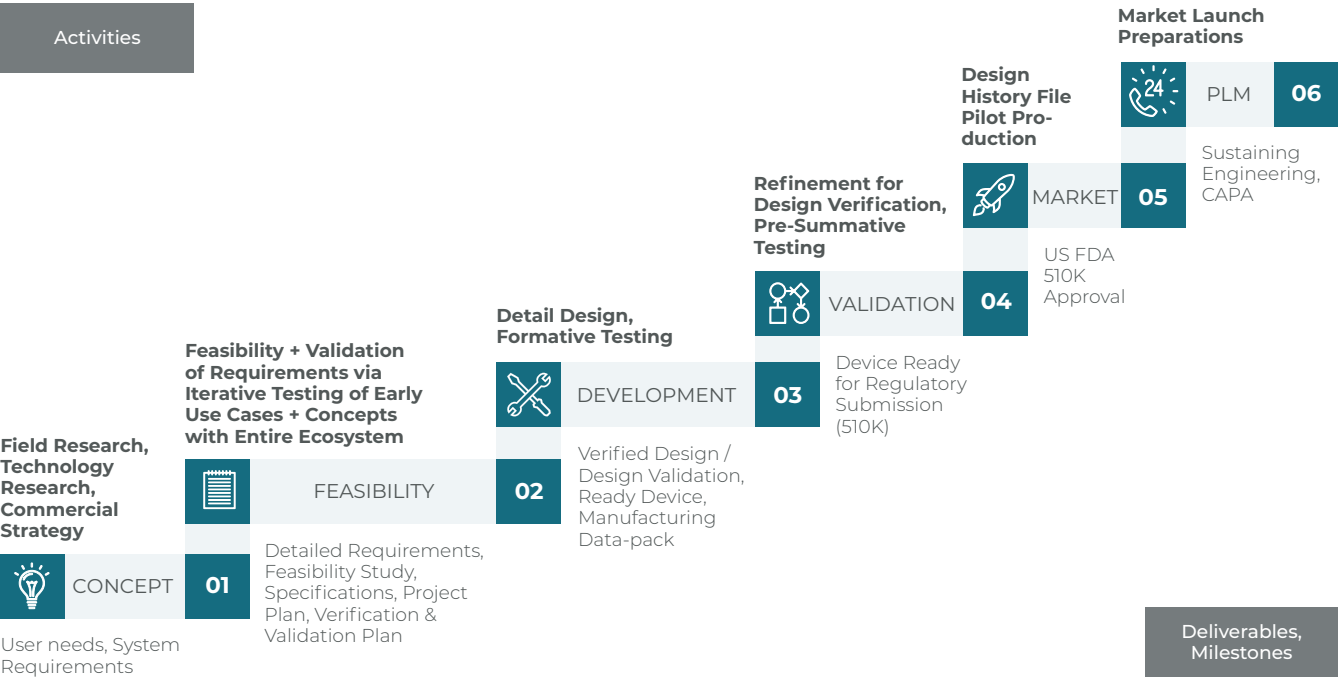


AUTOMATION OF SAMPLE PREPARATION FOR PROTEOMICS

The fast-growing field of proteomics enables new therapeutic approaches such as better targeted cancer treatments and antibody therapies. Accurate analysis of cellular protein patterns enables detection of pathological changes and close monitoring of treatment efficacy. To date, automated proteome analysis has been hampered by complex and unreliable sample preparation. This is where an innovative approach by a Munich start-up company comes in. Their method halves the number of process steps and reduces the time required by a factor of 20.

HSE supported the scientists so that the method could be implemented in instruments tailored to the specific needs of clinical and scientific laboratories. The wide-ranging experience of HSE developers allowed them to adapt an established nucleic acid platform to the needs of protein chemistry. As a result, timelines and costs were significantly reduced and the project risk was also lower compared to the development risk of a new system.

WE DRIVE ALL PHASES OF SYSTEM DEVELOPMENT



systematic way. In retrospectives, we also regularly discuss how we can further improve our teamwork. From my point of view, motivation plays an immensely important role in the agile approach. Motivated employees put more thought into things and think more creatively, and that is essential when solutions are needed that go beyond simply implementing standards.

Do the approaches differ for smaller projects and complex projects where many teams need to be coordinated across multiple sites?

The methodology is essentially the same for both complex and simpler projects. Larger projects are usually composed of several subsystems, each of which can be treated as its own small development project. This requires an additional layer of coordination. It is important in these parallel processes that the subsystems are run as self-contained units. This is necessary because otherwise the number of communication partners explodes and the developers have to spend more time reporting to each other. I've seen project teams that actually spent four out of five workdays on nothing other than communication.

In your opinion, what are the most important tasks that the client needs to fulfil for a development project to be successful?

There are three important things, a client needs to consider. Firstly, before the project is even launched, the client needs to be clear about what their objectives are and these need to be written down in a clear and concise way. This is not

LEADING GLOBAL PROJECT TEAMS TO SUCCESS

Last but not least, the project team and the engineers' experience are key factors in the success of development projects, especially when team members are spread across multiple locations. Over the last 20 years, HSE specialists have transformed numerous global development projects into technically and economically successful products and they have continually improved the procedure they follow.

HSE defines the project structures and processes together with its clients. Crucial for this is that the interfaces between work packages and specialist departments are defined right from the start and minimized wherever possible. This is because each additional interface means additional communication work. A clearly structured communication plan ensures constructive dialog with regular videoconferencing as well as on-site presence with the client during critical phases. Use of modern infrastructure options ensures rapid access to information for the entire project team at all times. All tasks are managed via a central tool. To support collaboration and ensure a systematic approach, HSE uses state-of-the-art technologies for visualization of the core functions of subsystems and modules, 3D modelling of mechanics and housing and GUI simulation. Clients are also regularly provided with prototypes that they can use to check the progress themselves.

just a compulsory exercise – it is absolutely crucial to the success of the project. The various stakeholders need a common vision to ensure that everyone thinks and acts along the same lines. Secondly, the client needs a project owner who has decision-making authority and sufficient domain knowledge. In my experience, pure project managers without domain knowledge do not really function as project owners in our environment. They lack the know-how needed to assess the work and give direction. The inevitable consequence is that wrong decisions are made. The third point concerns the project objectives. Managers in other areas may be used to pressure and unrealistic timelines leading to better results. But in

complex development projects this can be fatal, because people don't think faster when they are under pressure. On the contrary, it means that better solutions are not pursued because they don't fit into the tight timelines. If the quick fix that is chosen turns out to be a dead end, it's too late to do it all again and the next presumed shortcut will be taken. The project then ends up in a downward spiral. Incidentally, the main reason for unattainable and, thus, demotivating objectives is often that budget projections and timelines are set too early. A robust, risk-based evaluation is only possible after what is known as the Design Input Lock, when the requirements from the marketing team have been finalized, their feasibility has been

demonstrated by the development team, and they have been aligned and reduced to the absolutely necessary requirements.

Do you have any guidelines for reducing requirements to what is absolutely necessary?

The objective of the first product version should be the so-called Minimal Viable Product (MVP). It should be limited to key customer needs, but it must also function properly. Teams that restrict themselves in this way can bring prod-

ucts to the market much faster, which is crucial in today's competitive environment. It's important that the first version also has a clear roadmap showing how the product's functionality can be continually expanded. The equation is simple: the more functions that are built into the first version, the greater the number of sources of error. I once observed the development of an instrument that was designed as an absolute masterpiece of technology and covered every conceivable need. However, the enormous complexity led to a

large number of failures among early users. These days, no company has time for that and ingenious instruments quickly become forgotten about. Our responsibility is to always challenge the client and ask whether each of the planned functions is really necessary. In the same way, we also alert the management board when we realize that the project lacks a common vision. This benefits us, too, because we usually commit ourselves to a fixed cost and timeframe based on the Design Input Lock.



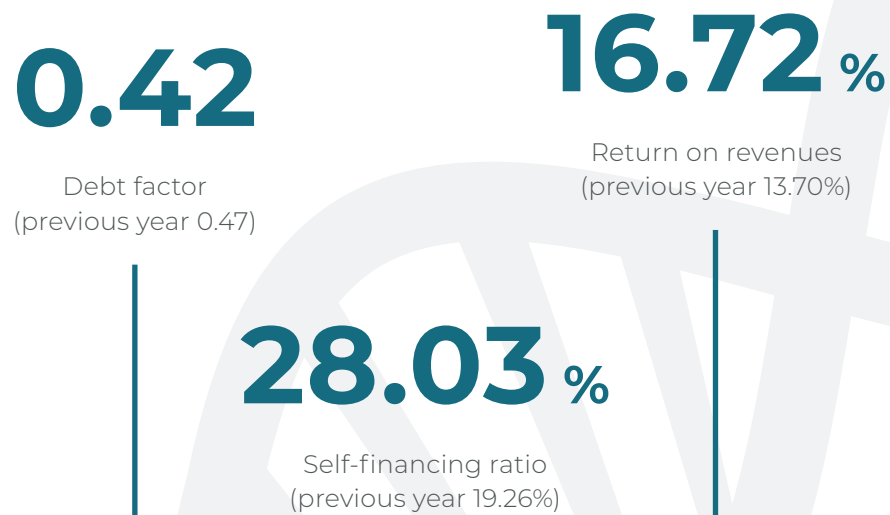
Facts & Figures for the 2018 financial year

The success enjoyed in the first year continued seamlessly in 2018. Sales and profits increased. The number of employees increased slightly and the turnover rate reduced to the standard industry level. The structures put in place back in 2017 demonstrated their functionality.

Key figures

In its second financial year, HSE AG was able to increase its revenues by 8.5% compared to its successful first year, to **CHF 8,673,741** (2017: adjusted services purchased: CHF 7,988,262). This resulted in a net profit of CHF 1,432,173 (2017: CHF 1,377,776), which corresponds to a return on revenues of 16.72%. Of the net profit, CHF 892,173 was paid into the pension fund as an employer contribution reserve (2017: CHF 1,200,000). This represents the maximum amount HSE can pay in. The resulting net profit was **CHF 558,056** (2017: CHF 177,776).

This business result gave rise to the following key figures:



Appropriation of profits

| | | 2018 | 2017 |
|---|------------|----------------|----------------|
| Retained earnings, beginning of fiscal period | CHF | 168,776 | 0 |
| Net profit | CHF | 558,056 | 177,776 |
| Available retained earnings | CHF | 726,832 | 177,776 |

The Board of Directors proposes to the General Meeting that the profit be appropriated as follows:

| | | 2018 | 2017 |
|------------------------------------|------------|----------------|----------------|
| Payment of a dividend of | CHF | 0 | 0 |
| Allocation to the legal reserves | CHF | 11,000 | 9,000 |
| Allocation to the free reserves | CHF | 0 | 0 |
| Carried forward to new account | CHF | 715,832 | 168,776 |
| Available retained earnings | CHF | 726,832 | 177,776 |

Audit of the financial statements

The financial statements of Hombrechtikon Systems Engineering AG for the financial year 2018, which covers the period from 1 January 2018 to 31 December 2018, were audited as at 15 March 2019 by Treu-control AG as external auditors in accordance with the Swiss Standard on Limited Audits.

Risk assessment

In the first year of its existence, HSE established a quality management system as per ISO 13485:2016 for the development of in-vitro diagnostics (IVD) systems. This was certified in November 2017 and the first audit was successfully passed in 2018. Risk management is an integral component of this system.



To identify both risks and opportunities at an early stage, HSE regularly reviews internal and external factors across the entire corporate environment. The financial data determined for the financial statements in accordance with the Swiss Code of Obligations and the risk-related financial figures in accordance with the regulatory requirements form the basis for this review.

Employee competencies

HSE has an exceptional breadth and depth of expertise among its staff. Its employees come from **11 different countries**. Their competencies cover the entire spectrum of technology and project implementation requirements for the development of life science and diagnostic solutions based on molecular biology. In combination with many years of experience, they represent a crucial competitive advantage for HSE.

Employee development

The number of employees at HSE increased slightly in 2018, from 49 to **52 employees**. Of these new staff members, three are apprentices (one design engineer, one commercial apprentice and one IMS trainee), resulting in an **apprentice ratio of around 5.8%**. This is above the Swiss average of 4.7% of all employees (2016).

Employee development was supported through various workshops and events in 2018. Goals here included reinforcing the sense of responsibility of each employee and building bridges between management and employees. This should help to en-

sure that the organization can adapt in an agile way to client needs.

The turnover rate was reduced to 10% in 2018.

This means that in its second financial year it is already at a standard industry level. In the previous year, turnover was still at 20% due to the extreme changes associated with the transition from a large group entity to an independent start-up company. The fact that all vacancies due to turnover have been filled and additional employees have also been brought on board shows that HSE is well positioned in the extremely competitive international labor market for highly skilled professionals.

Employee participation program

An important cornerstone for HSE's long-term business success is the employee participation program launched at the end of the first financial year. Selected employees can acquire participation certificates through this program. Their value is strongly linked to the success of the company. The purpose, detailed participation conditions and calculation of value of employee participation are documented in the program regulations.

After the second financial year, the value of the **participation certificates is 8.35832 times** (2017: 2.77776 times) the original nominal value of CHF 0.01. Employees will be able to acquire further participation certificates in 2019. Around 80% of HSE employees have taken the opportunity to participate in the company to date. This high proportion shows that employees also have great confidence in the sustainability of HSE's business model.



“I find the process of understanding client needs to be really fascinating. Whether it's bringing a novel technology to market rapidly and reliably, or extending the life cycle of a product and ensuring it's in line with the current state of the art.”

Peter Bösch, Senior Platform & Project Manager HSE AG

“The various areas in which HSE operates and the high corporate standards create a professional and challenging work environment. The abilities of each individual employee are identified and promoted.”

Rafael Novotny, ICT Trainee HSE AG

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