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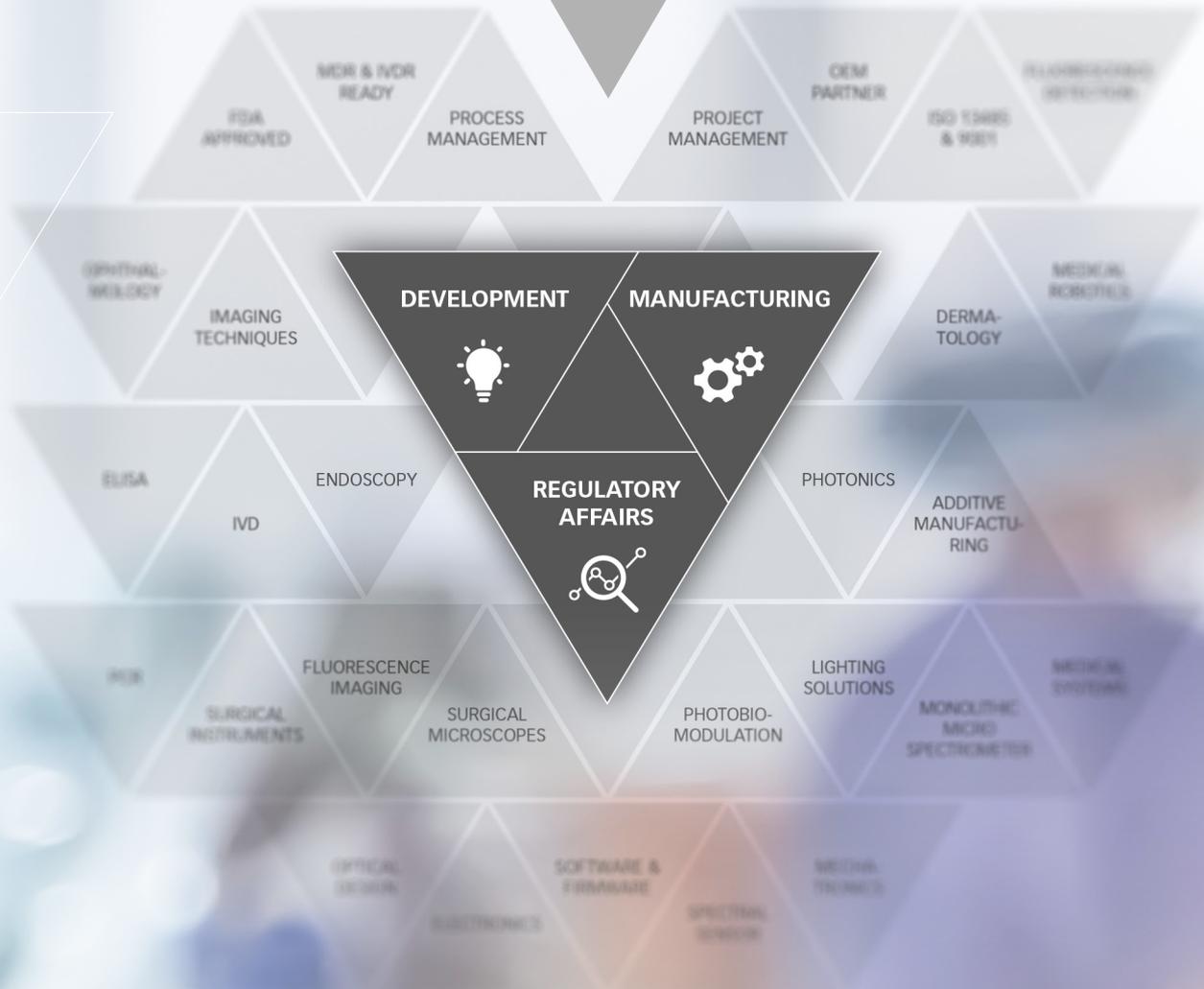


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PRISMA

The WILD Group
magazine



BUNDLED NETWORK EXPERTISE IS A WINNING ARGUMENT




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PRISMA

AGILE DEVELOPMENT METHODS.



Wolfgang Warum
 Managing Director CTO
 WILD Group

There are several factors that determine the success of a development project. Requirement management is one of the key disciplines. The times when product development would begin with clearly formulated requirements are long gone. Today, new business models and products emerge at breath-taking speeds. The framework conditions are changing faster than ever before. To keep pace despite all of the developments, you need modern, agile project management. Together with our WIN network partner Stephan Richter, a renowned organisational development expert, we have developed a toolset that opens completely new possibilities. For more on this, read our article on „Greater agility, better products“. At the same time, however, agile approaches will only lead to validatable results when they are based on in-depth process knowledge.

Our article „Repeatedly accurate quality“ describes how much know-how and experience the WILD Group contributes in this area.

This also plays a crucial role in sterile production, where the WILD Group has supported its customers in the development and manufacturing under bacteria-controlled conditions for several years - with outstanding success.

All in all, WILD and Photonic have solutions ready for a hugely diverse set of customer requirements. Take the opportunity to meet us at the COMPAMED/MEDICA 2021 in Dusseldorf and give us an insight into your challenges. We look forward to many constructive meetings with you.

Wolfgang Warum
 CTO WILD Group



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STERILE FOR SURE.

The WILD Group has in place the bacteria-controlled environment required for production and a well-integrated network of experts for the development of its sterile products.

Sterility is a valuable asset in hospitals. This applies in particular to devices that come into direct contact with patients. Especially in the case of active medical devices with complex electronics, one factor stands out as crucial: These must be designed and produced in a manner that renders them sterile and capable of withstanding several sterilisation cycles. "WILD possesses the expertise and, in addition, a reliable network of partners to develop precisely such sterile products and manufacture them in a bacteria-controlled environment", stresses Stephan Payer, Head of Business Unit WILD Electronics.

DEVELOPMENT WITH STERILISATION IN MIND

The sterilisability of complex medical products featuring connections and control interfaces depends especially on two factors: "Already during development, you must design the product to ultimately allow for its operation to withstand multiple sterilisation cycles. In addition, it is necessary to timely select the correct cleaning procedure for the corresponding application", Payer explains.

To guarantee the reproducibility of function and quality, the company uses a proprietary process for bacteria-controlled manufacturing. "Our strength lies in the fact that we cover the entire process chain from product development and assembly to the final tests and packaging. This is why our expertise is so much in demand, in particular for high-end products with a very low bacterial load", stresses Alfred Michalek, Head of Quality Management at WILD Electronics.

HAND-PICKED SUPPLY CHAIN

To guarantee such a low load, you must apply extremely strict requirements already in the selection of the basic materials and their suppliers. Over the years, WILD has built up a distinguished network of qualified partners who meet GMP-compliant hygiene standards. For instance, materials are introduced into the bacteria-controlled space already upon delivery. Assembly takes place under operating theatre conditions with the corresponding protective clothing, a competent laboratory provides the necessary approvals and the WILD staff regularly attend hygiene training courses. "Moreover, the environment conditions must be re-qualified and re-validated with each manufacturing batch. Overall, the manufacture of sterile products is therefore a very complex process that we have mastered over several years and which allows us to guarantee a quick time to market for our customers", says Michalek.

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GREATER AGILITY, BETTER PRODUCTS.

Especially in development, agile project management often decides who holds the competitive edge. Together with organisational development expert Stephan Richter, WILD is taking a completely new approach in this regard.

There are situations that developers are familiar with but that still present a true challenge for others: Product requirements that are basically nothing more than just rough guidelines. Projects that, at the beginning, don't go beyond the mere description of an idea. Specifications that are changed at a very late stage. Or requirements that are suddenly no longer relevant. Following an intensive study of the topic of agile project management, the WILD Group has learned how to deal with these issues.

Moreover, with the support of organisational development expert Stephan Richter, WILD adopts methods already established, among others, in the automobile industry and takes these a step further. „Based on the concept of systemic project diagnostics, we begin by analysing the requirements and the complexity of a project. And we do so both on a technical and on a social level“, explains development manager Michael Reissig.

„Depending on the result, we choose the right toolset to avoid breaking a butterfly on the wheel. The objectives of the customers, who usually set clear priorities on engineering, costs or timing, also determine the methods to be applied: from simultaneous engineering and the Cynefin framework for complex problems to the classic waterfall

model“. As a result, WILD is an agile and valuable partner in all development issues. From ideas to devices. From prototypes to serial production.

BEST-PREPARED FOR THE TECH ONSLAUGHT

Stephan Richter, who is working together with WILD on the improvement of this toolset, explains why this flexibility is becoming ever more important: „We are currently experiencing a technology onslaught and we often see that a high degree of uncertainty prevails in development. Of course, there is always a standard area, where the objective and the course are clear. It is outside this standard that things get more exciting. Where there is a requirement but no one knows yet what the solution

should look like. This is where common sense is required. You need to take a creative approach and bring the people to the resources so they can work in a targeted manner. It takes completely new tools and other forms of communication to do that.“

Asking the right questions. Using

classic tools like milestone planning to provide security where orientation is needed. Identifying regulatory circuits to harness their advantages for the project team. WILD has a whole range of methods at its disposal, allowing it to work with great efficiency and ensure a quick in-depth insight into a project.

“ In future, the devices themselves will be less important for the customers, and functions will be front and centre. This is exactly where WILD's basic intelligence lies.

Michael Reissig, Development Manager



„This strong customer focus is part of the WILD Group’s DNA. As a result, it is easy for me to deliver new impulses with the improvement of various tools which are implemented immediately”, says Richter. Another trait that makes the technology partner stand out is the group’s focus on resources. In addition, WILD created the WIN partner network several years ago with the aim of bringing more know-how into the group. The example of a digital surgical microscope demonstrates how well this works in practice. The interdisciplinary development tasks - software, electronics, mechanics and optics - were spread across the production sites in collaboration with the customer. „We allocated resources to where they would have the most efficient impact on the project plan. Essential decisions were discussed and taken in a large group so as to eliminate waiting times”, Project Manager Manuel Pruntsch explains. The short sprints and almost daily coordination meetings across all expert departments provide the customer with „live” information about the ongoing progress and allow for the development project to be implemented as efficiently as possible.

What about the future? „We intend to adopt an even more function-oriented attitude and approach”, stresses Michael Reissig. „In future, the devices themselves will be less important for the customers, and functions will be front and centre. This is exactly where WILD’s basic intelligence lies. We are capable of translating functions into components. At the same time, we analyse in detail which requirements bring added value for the customer and which ones we can put last”. A current example from medical technology demonstrates how WILD can very quickly adapt a high-value product and launch it on the market.

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HIGH IN DEMAND

Mechanical engineering graduate and psychologist Stephan Richter is an expert in organisational development and project management. He assists the WILD Group in the creation of an innovative toolset for agile project development.

HOW CAN HIGHLY COMPLEX DEVELOPMENT PROJECTS SUCCEED?

The project management must have an impact both on a technical and a social level. In addition to all the technical requirements, it is most of all necessary to look at the people working on a topic, with all their influences, ideas, qualifications and resources. Especially in the case of projects that require flexible and innovative approaches, it is worth looking at what the employees are capable of, what they enjoy doing and where their potential lies. You can take these resources and generate high motivation and a more targeted work approach.

HOW DID YOU EXPERIENCE COOPERATION WITH WILD SO FAR?

The WILD Group is a quintessentially dynamic company. Very curious. Transforming knowledge into daily practice happens unbelievably fast. This makes it easier for me to provide new impulses. The project teams adopt the tools I propose immediately in their work. As a result, it is tremendously easier to initiate change.



REPEATEDLY ACCURATE QUALITY.

If you want to ensure the highest possible product quality throughout the entire product cycle, you should have a development and manufacturing partner at your side with the necessary expertise in process validation.

DEVELOPMENT | PRODUCTION

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The ultimate aim of every contract manufacturer is to manufacture a product that is free of defects. In medical technology, however, the goal goes far beyond that: You must guarantee that the product meets strict regulatory requirements and that the manufacturing processes were safely developed to ensure reliable performance throughout the entire lifecycle. „The relevant regulations, whether ISO 13485, 21 CFR Part 820 or the EU Regulation on medical devices, are basically the same for everyone. Yet the customer’s specifications often vary significantly. This is why WILD makes sure to guarantee quality as early as possible“, NPI Quality Engineer Markus Lippe explains. A current development project for a surgical instrument stand demonstrates the advantages this can bring.

„We identify details at an early stage during risk analysis, which we can eliminate without great effort, so they no longer cause any difficulties once we go into serial production.“ However, it is not rare to have customers approach WILD already during ongoing serial production. Recently WILD digitised the test method for a device used in the measurement of vital functions according to the customer’s requirements and in compliance with the regulatory provisions. „This allowed us to rule out another source of errors and achieve a genuine efficiency gain“, Lippe stresses.

PROCESS VALIDATION ALSO FOR OPTICS AND INDUSTRIAL PROJECTS

For industrial and optical technology companies, process validation is also increasingly moving towards centre stage. “For them, it is equally critical that WILD manufactures 100% according to

specification. Therefore, we are increasingly resorting to initial sampling including documentation to obtain the necessary evidence with regard to dimensional accuracy, material composition, surface quality and much more.”

At the end of the day, both quality and documentation must be up to standard. This is only possible through proactive quality planning and professional process validation, plus ongoing process reviews. The underlying condition for any validation is a risk analysis to determine the scope of validation. The installation qualification verifies that the facilities, machinery

and equipment correspond to the manufacturer and process descriptions, and that they were correctly installed. Operation qualification ensures that the system is working in accordance with the specifications. During the subsequent performance qualification, WILD furnishes

proof that the process functions in a stable manner within the predetermined limits. The same applies to any modifications to the product. Where the customer carries out such modifications, WILD performs a re-evaluation.

We identify details at an early stage during risk analysis, which we can eliminate without great effort.

Markus Lippe, NPI-Quality Management

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BUNDLED NETWORK EXPERTISE IS A WINNING ARGUMENT.

The relaunch of MEDICA/COMPAMED 2021 sees a sizeable WILD Group presence and a whole host of innovations.

How can you combine different ideas to create an innovative product? Moreover, what distinguishes those specialists who develop and manufacture such high-tech devices using their experience, know-how and technical skill? The WILD Group will deliver illustrative answers to these questions at the MEDICA/ COMPAMED trade fair from 15 to 18 November 2021, offering visitors a glimpse behind the scenes of its success. And not only at the trade fair itself, where the senior management, members of the technical and business development teams and CTO Wolfgang Warum will be present. „In addition, this year the group’s development and production sites will be virtually present at the trade fair“, explains Heidrun Freimuth, WILD’s expert for marketing and trade fairs. Potential new customers in particular will thus obtain a direct feel for how WILD works.

„Following two years without a trade fair and countless online meetings, we are really looking forward to a live relaunch of the real-life event, where we can exchange ideas face to face with experts and manufacturers on the latest technologies from the areas of medical & life sciences, in-vitro diagnostics and laboratory, laser and lighting technologies. This is why we took the conscious decision to send a large team to the fair“, says Freimuth. Exciting products from WIN network partner INSION GmbH will be complementing the trade fair portfolio of WILD and lighting specialist Photonic. The company is among the leading makers of monolithic microspectrometers

and spectral sensors for OEM applications and miniature glass fibre optics.

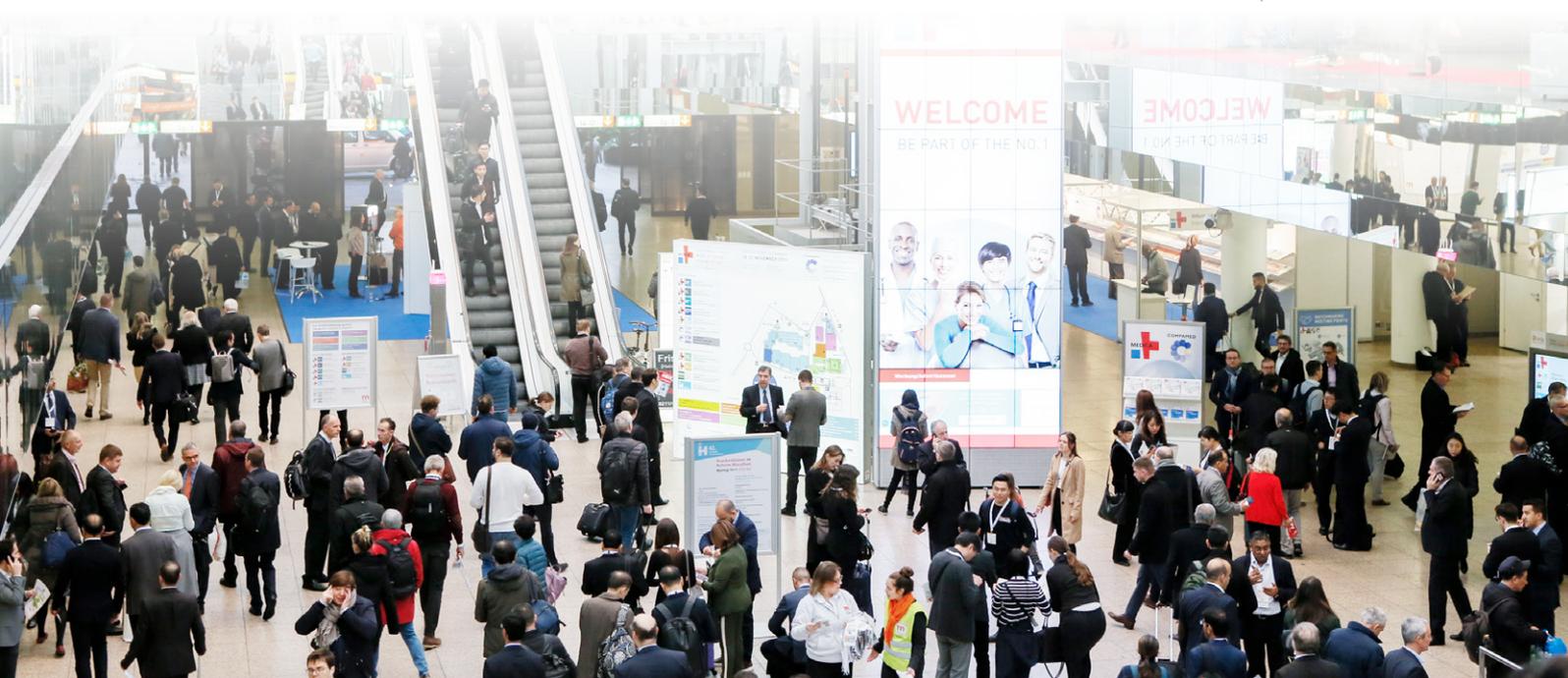
A LOOK INTO THE FUTURE OF MEDICAL TECHNOLOGY

Two WILD experts will be present as part of the COMPAMED Suppliers Forum, to provide in-depth information on the topics of outsourcing and fluorescence technologies. On Monday 15 November, Business Development Manager Daniel Pressl will be speaking about the importance of outsourcing as a solution for the development and production of high-tech medical products. And, on Tuesday 16 November, Photonic Business Developer Joachim Enengl will be explaining the immense solution potential of fluorescence technologies. Using a set of different examples, he will be providing some insights into the photonic and optomechatronic engineering and manufacturing know-how applied by Photonic in the optimisation of diagnostic and interventional devices.

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IT'S WORTH DROPPING BY!

FAIR

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Take advantage of the inspiring setting of COMPAMED/MEDICA to talk about your future projects with experts from WILD, Photonic and our network WIN partner Insion. Either directly at our booth in hall 13 / booth D45, on a virtual tour of our development and production sites or in the COMPAMED Suppliers Forum.

Immerse yourself in our world of medical & life sciences, in-vitro diagnostics & analytics and laboratory, laser and lighting technology.

OUR EXPERT PRESENTATIONS AT THE COMPAMED SUPPLIERS FORUM

- ▽ Daniel Pressl, Business Development WILD
on 15 November 2021 from 11.00 to 11.30 a.m.
„Why is Outsourcing the Solution to Current and Future Challenges of High-Tech Medical Device Development and Manufacturing“
- ▽ Joachim Enengl, Business Development Photonic
on 16 November 2021 from 11.00 to 11.30 a.m.
„Fluorescence: Technology for Personalized and Precision Medicine“

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THE WILD GROUP

The WILD Group is comprised of the WILD brands which are established in Völkermarkt and Wernberg (Austria) and Trnava (Slovakia), as well as Vienna-based Photonic. The technology partner develops and produces optomechatronic systems for medical and industrial applications as well as optical technologies exclusively on behalf of its customers. Approximately 500 staff members are always the first choice whenever precision and reliability are called for and wherever innovation takes place.