# WELCOME TO OUR FIRST NEWSLETTER





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# Introducing GCPS official newsletter-Issue 1.0!

The aim of this newsletter is to inform our clients, vendors, collaborators, followers and associated partners regularly with latest updates in our contribution to the clinical research spectrum!

We also want to introduce you to our new and improved services, and overall develop an insight into our daily commitment and strive to be better.

We hope you enjoy reading it and follow our journey.

## **CHANGES IN MANAGEMENT**





From 1st July 2022, GCP-Service welcomed a new CEO, Dr. Andreas Beust. He most recently held the position of Chief Scientific Officer and now succeeds Dr. Andreas Grund, the company's founder, who handed over his CEO role after 18 years.

After completing his PhD, Andreas Beust, also known to the GCPS Team as Andi, began his career at GCP-Service in 2017. Starting as a biostatistician and data manager, he progressed through a variety of positions.

instrumental in further strengthening the GCP-Service brand, advancing and developing the services, particularly in the area of biostatistics and their pivotal role in clinical trial planning and conduct.

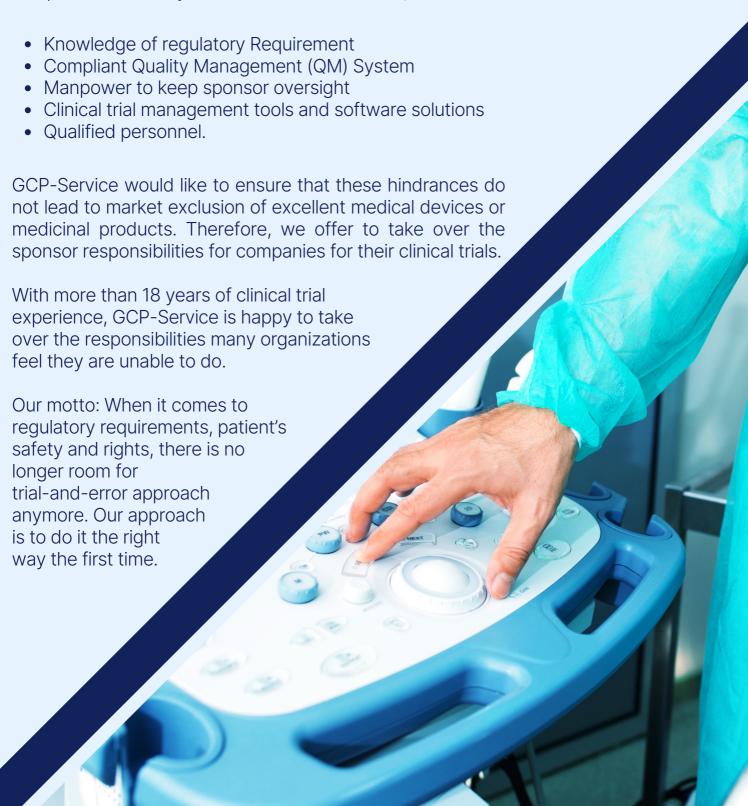
We are incredibly pleased that he will now be contributing his incredible knowledge, his never-ending passion and his innovative ideas in this new position and look forward to the future together.



# **NEW SERVICES**

### **SPONSORSHIP AS A SERVICE®**

With the recent releases of ICH E6 (R2), ISO14155:2020, MDR and IVDR, the European clinical research space has seen an increase in regulatory complexity of clinical trials that leads some companies to question the feasibility of trial conduct as Sponsor. This may be due to several reasons, such as lack of:



# **NEW SERVICES**

# GCPS INVESTS IN MEDICAL DEVICE STARTUP COMPANIES



2022 continues to be a ground-breaking year for GCPS as it ventures beyond its core CRO business.

In March 2022, GCP-Service invested in a small medical device startup company focussing on skin diseases through e-health technologies. We have always believed in innovating products that leverage patient health and quality of life, hence we look forward to this development and more in the wide world of medical technology and medicinal products!

The advantage is obvious: especially young manufacturers need support in setting up their operations in a regulatory requirement compliant way, and to navigate the path to market entry. Additionally, they need support financially organisationally and in terms of strategic concepts. Closer cooperation in this area ultimately produces fruitful results for both sides.

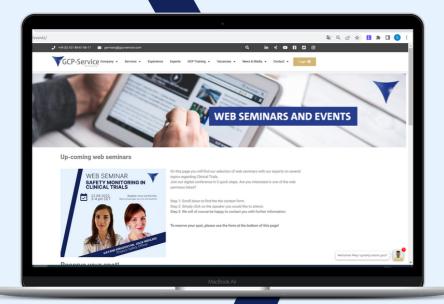
From now on, GCP-Service supports them in a renewed role, so that their ground-breaking ideas do not fall by the wayside but becomes a successful model.





Web seminars are on everyone's lips. They are a way of presenting content in real time to an audience digitally and at the same time come into contact with people from all over the world. In the last two decades, we have experienced that the entry into clinical research is associated with high hurdles for many manufacturers. But we also want to share our knowledge: the more we talk about how we feel things should work and what our own lessons learned are, the more the quality of our work increases and the more the patients benefit from better treatments being developed in a faster and higher quality manner.

We have had various experts - including the new CEO, Dr. Andreas Beust, our new Chief Operating Officer, Thomas Kissner, Head of Quality Assurance, Petra Stepankova, Chief Interface Officer, Dr. Marco Schwarzer and Regulatory Affairs Manager, Dr. Alexandra Ortiz Rodriguez, dive into crucial topics providing useful and interesting insights into their expertise.



From risk-based monitoring and quality management to data management or audit and inspection readiness, IVDs and more, various mosaic stones of clinical trials were included.

And GCP-Service is not finished yet. The next ideas and topics are already in the pipeline for the second half of the year. So look forward to it and check out the latest news on our website!



# **ABOUT US**



GCP-Service is not your typical CRO: We offer all clinical trial services enabling smooth conduct of clinical studies from planning, start-up, patient recruitment, trial conduct, until close down. We also offer unique niche stand-alone services supporting in other aspects of clinical research such as legal representation & GDPR in EU, UK and EEA, ICH GCP/ISO 14155 certified trainings for companies and individuals, technology service provider, site management services (through GCP-Derma Service), global support via AlCROS and free educational content on

our GCP-Mindset channel on YouTube. Legal Representation / GDPR **Biostatistics Clinical Data Management Clinical Operations Project Management** Product Vigilance Service Regulatory Affairs **Medical and Scientific Writing** Sponsorship as a Service (SpaaS® **Medical Devices and IVDs** Trial Master File Management **THANK YOU!** 

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