Who we are

Welcome to incantis GmbH,

a team that will hit the ground running!

We are motivated, flexible and creative and will support you with whatever task may have come your way!
Not only will we be aiding you in finding solutions to your problems and concerns, but also supporting the concrete implementation of the necessary documentation and trainings to ensure long-lasting stability of the effects of our work.

Since the company's founding in 2009, our young team will bring you the fresh ideas and modern solutions you are looking for to ensure conformity not just today, but tomorrow.

Using our experience working with companies all over the medical devices/pharmaceuticals industry and in contact with our wide-ranging international network of colleagues, no problem will be left unsolved!

If you would like to know exactly who we are and what we can do for you, the next pages will give you more insight into the company.

Thank you,

Julia Wolfrat
CEO

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Our areas of expertise

QMS Implementation

Supporting the creation of a new QMS for startups

Gap Analysis of current QMS

Audit preparation and remediation regarding

- ISO 13485 & 21 CFR 820
- MDD to MDR,
- ISO 9001/13485 recertification

CAPA, Complaint handling and Change control coordination

Internal audits of production or single departments

Mock system audits

Implementation of new or adapted processes and creation of accompanying documentation

Review of batch records for correctness and completeness

Evaluation and graphical representation of data for Management Review

Technical Writing

Creation and translation (German/English & English/German) of technical (e.g. verification, validation, biocompatibility testing) documents and QMS documents of any kind

Reports and attachment documentation for Change Control and Deviation Management purposes

“Translation” of technical information into QMS documents and vice versa

Editorial work on completed documentation

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Validation	Creation and completion of DQ, IQ, OQ, PQ, PV documentation as well as framework documents in Process and Design Validation Preparation and management of PQ and PV test runs including presentation of results Creation and implementation of Design Validation process and relevant documentation Evaluation and assessment of validation document regarding suitability for specific purpose
Training	Training material creation and training delivery of QMS trainings as well as trainings in the usage of a (specific or general) document management system
Project Management	Creation and management of overall project document plan and project management tracing (e.g. coordination of inputs and timelines) On-boarding of new colleagues Management of availability of valid versions of documents Moderation of recurring meetings to ensure collaboration of QM and Engineering

The **incantis Document Control Team** is here to make everything related to documentation a lot smoother and more efficient, making sure your experts can focus their time where they are needed most and project resources are not spent on organizational tasks.

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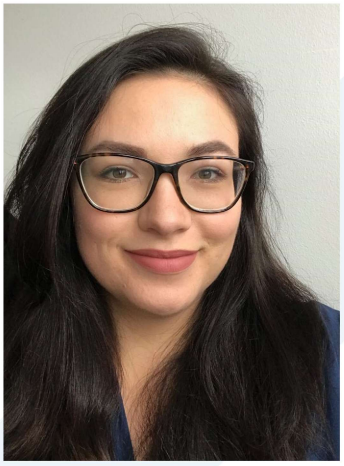
Julia Wolfrat | Consultant/CEO



Close to 10 years of experience in the industry gained in various projects including devices of all risk categories as well as MD Software make Julia your ideal choice for establishing or restructuring your QMS while closely coworking with your different departments.

Certifications:

- **2021** IEC 62304
- **2020** ISO 14971:2019 (BSI)
- **2019** MDD to MDR transition (BSI)
  Internal Auditor ISO 9001 (BSI)
  ISO 9001:2015 (BSI)
- **2018** MDSAP (TÜV Süd)
  Internal Auditor ISO 13485 (SNV)
  ISO 13485:2016 (TÜV Süd)
- **2017** Regulatory Affairs Manager International (TÜV Süd)

Focus:

QMS creation and remediation

Process/Design Validation

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Florian Maier | Consultant

With more than 20 years of experience of working in the Medical Device industry in various roles such as Technical Manager, QMB, Business Development Manager and others, Florian has broad knowledge of Quality Management in general, as well as production-specific.

Certifications:

- **2019** MDR transition (TÜV Süd)
- **2009** Regulatory Affairs Manager (TÜV Süd)
- **2007** Spezialist Technical Documentation (TÜV)

  Medizinprodukteberater und Sicherheitsbeauftragter MPG
- **1998** Quality Manager (DGQ)
- **1997** Internal Auditor (DGQ)

Focus:

QMS Implementation in production

Internal audits

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Andrea Wonner | Junior Consultant

Andrea's Bachelor of Science in Medical Engineering has been a great foundation for her two years of experience in the MD industry, which include work on Quality Management Systems as well as Technical Documentations and regulatory submissions.

Certifications:

- **2021** IEC 62304
- **2020** ISO 14971:2019 (BSI)
  ISO 13485:2016 (BSI)
- **2019** MDD to MDR transition (BSI)

Focus:

QMS/Technical File remediation

Software Validation

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