ANTERIS MEDICAL

Global Medical Device Support Meeting Your Needs

- combination products (acc. to 21 CFR part 3/4 and MDR Art. 117)
- in-vitro diagnostics and other medical devices
- ISO 13485 certified
- customer support from our locations in Germany, Switzerland, the US (starting 2022), and virtually around the globe
- technical documentation
- global product registration
- compliance and quality management

anteris [Greek] = support

Your consultancy for combination products, medical devices, and IVD products during development, through registration and beyond.

anteris medical GmbH | münchner straße 47e | 83607 holzkirchen | germany

www.anteris-medical.com

anteris [Greek] = support

anteris medical supports their customers with their medical device challenges, during development, throughout the registration phase, and beyond.

anteris medical has been founded in 2014 and supports the pharmaceutical, biotech and medical device industries globally by managing the development of combination products, medical device products, or in vitro diagnostics. Our broad competencies cover compliance, regulatory affairs combined with innovative, resource-efficient solutions for compliant technical documentation, as well as marketing and sales expertise. We are life sciences and engineering majors with combined hundreds of years of experience in product development, CE marking, 510(k) submissions, and quality systems regulations in all major markets.

LIFE SCIENCES MEET MEDICAL DEVICES – A CHALLENGE

anteris medical has deep roots in both, the life sciences and in medical devices. We interface and translate between the two industries.

COMBINATION PRODUCTS

One key pillar of anteris medical's portfolio is the support of drug/device and biologics/device combination products. For combination product projects we manage development projects, provide regulatory affairs expertise, and provide quality consulting. Important product categories include prefilled syringes, needle-safety devices, autoinjectors, inhalers, and patch pumps.

MEDICAL DEVICES / IVD

anteris medical also has extensive knowledge in class II and III medical devices, as well as IVD products, and supports customers during every phase of the product lifecycle.

TOOLS

Compilation and maintenance of technical documentation often is a burden on the development organization. Anteris found a way to decrease the burden by the use of suitable software tools.

- **tachysCP:** the unique and unrivaled anteris solution for the development of combination products. The tool comes pre-configured with a library of requirements and risks specific for the most common combination products.
- **Matrix Requirements Medical:** the foundation of tachysCP and our strong recommendation for the development of any medical device or IVD. Matrix Requirements Medical features instant and intuitive use with minimal training, and flexibility ensuring compliance with regulations.

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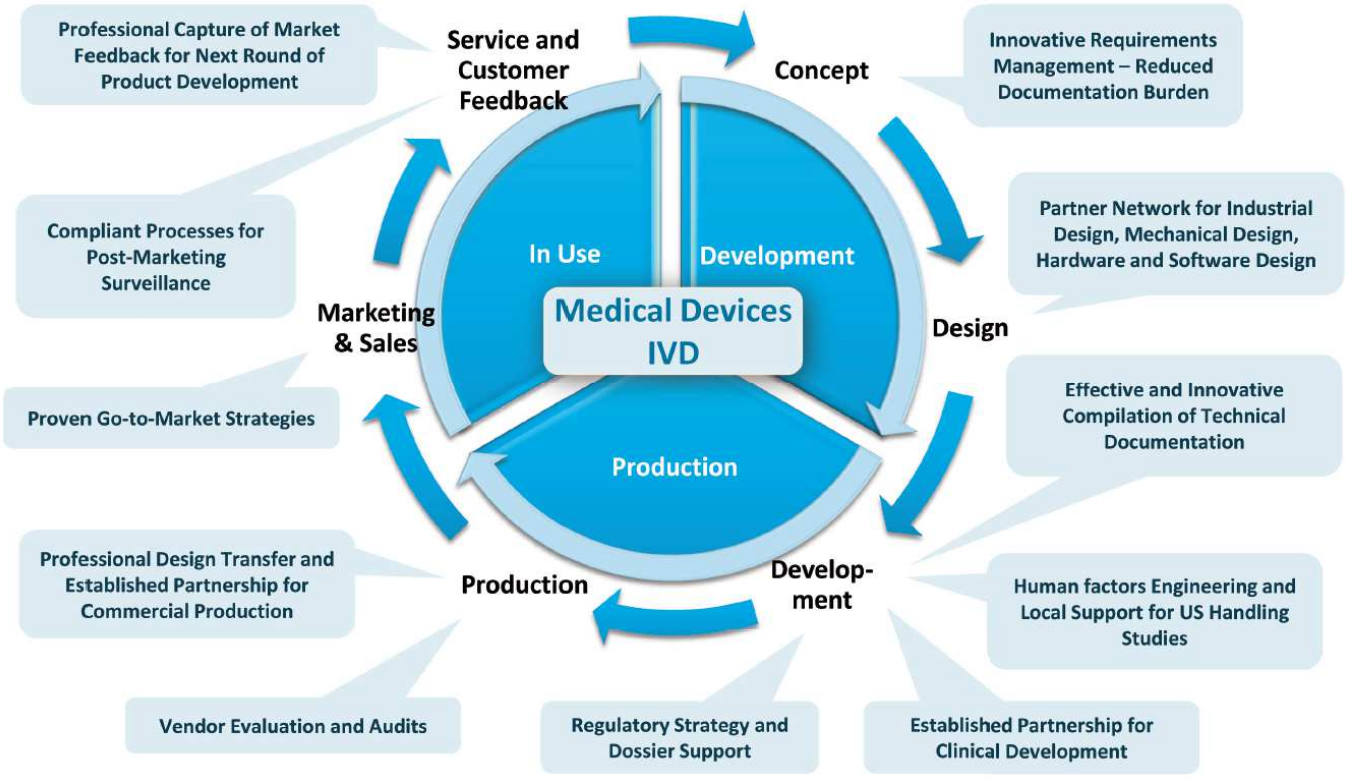
PRODUCT DEVELOPMENT – A CYCLE OF IMPROVEMENT

Effective project management throughout the entire product lifecycle, establishing and maintaining compliance with **ISO 13485**, the **MDR**, the **IVDR,** and **21 CFR 820.**



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Mastering the art of combination products

WHAT?

- Combination products: PFS, DCS, Pen, AI, OBI
- Quality management systems
- Medical devices
- In-vitro-diagnostics
- Digital health: Connected combined products

HOW?

- Global regulatory support
- Project management
- DHF/technical documentation
- Risk management
- Human factors engineering
- Packaging and labelling
- Competent authority interactions
- Lifecycle management

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Mastering the art of combination products

ANTERIS MEDICAL

ANTERIS HELVETIA

54 satisfied customers	**9** years in business	**300+** projects	**8** notified body opinion submissions
25 consultants	**6** locations	**15** languages	**287** years of experience in medical devices

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anteris medical

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Website ›	**www.anteris-medical.com**
Social Media ›	**in X**
Number of Employees ›	**29**
Founded (year) ›	**2014**
Areas of Activity ›	**| Combination products** **| IVD and other medical devices** **| ISO 13485 certified QMS** **| Technical documentation** **| Global product registration** **| Compliance and quality management support**
External collaborations ›	**| Acad group** **| ARQon** **| Assay.works** **| Baymar Solutions** **| Biopharma Excellence** **| Latini Group** **| Matrix Requirements** **| Medizone** **| Sourcia** **| ZebraSci**
Request for Further Collaborations ›	**| Medical Device Firms** **| Verification and Validation Testing Providers** **| Pharmaceutical CMOs**

We support our customers in their medical device challenges during development, through registration, and beyond.

Success results from connection – the connection of ideas, expertise, and experience. Anteris medical was founded in 2014 and supports the pharmaceutical, biotech, and medical-device industries globally by managing the development of combination products, medical device products, and in-vitro diagnostics.

Our broad competencies cover compliance and regulatory affairs, combined with innovative, resource-efficient solutions for compliant development and technical documentation, as well as marketing and sales expertise.

We are life sciences and engineering professionals with dozens of years of experience in CE marking, 510(k) submissions, and quality systems regulations in all major markets. Let's connect!

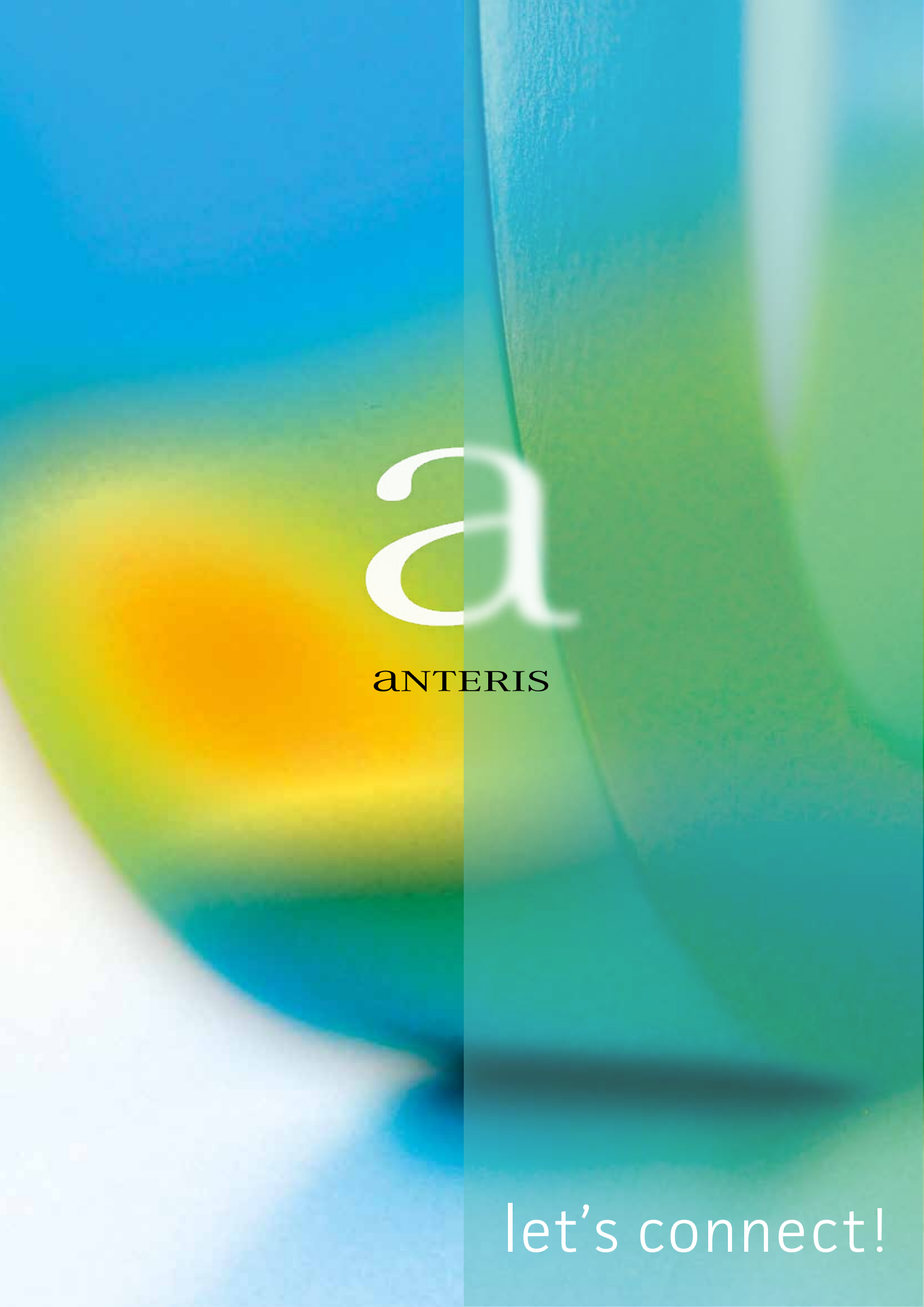
Anteris medical associates come from the life sciences and medical device engineering worlds – and thrive at navigating the interface between the two.

- Combination Products:
  One pillar of anteris medical's project portfolio is the support of drug/device combination products. Anteris medical has key competencies in project management, regulatory affairs, and quality consulting for autoinjectors, pens, and needle-safety devices.
- Medical Devices and IVD:
  Anteris medical also has extensive knowledge with class I, class II, and class III medical devices, as well as IVD medical devices, and supports customers during every phase of the product lifecycle.
- Tools:
  Technical documentation is easily managed by appropriate software tools, especially in the field of requirements engineering and documentation. Anteris medical can offer tailored and effective tools to make sure your DHF documentation is always up to date.
  - tachysCP: the unique and unrivalled anteris solution for the development of combination products. The tool comes fully packed with a predefined catalog of requirements and risks specific for combination product development.

- Matrix Requirements Medical: the bedrock of tachysCP and our absolute recommendation for the development of any medical device or IVD. Matrix Requirements Medical is the epitome of instant and intuitive use and flexibility, ensuring true assistance at any level of complexity.
- We are also experienced in the implementation of many other tools available in the market.

Effective project management throughout the entire product lifecycle: keeping projects on time, within budget, and in compliance with ISO 13485 and 21 CFR 820.

- Concept:
  - Structured, user-centered concept development
  - Innovative requirements management – reduced burden of documentation and improved traceability
  - Patient preference studies
- Design:
  - Partner network for industrial design, mechanical design, hardware and software design
  - Supplier evaluation and audits
- Design Control
  - Establishment of EU- and US-compliant development processes and documentation
- Risk Management
  - Implementation of risk management processes in accordance with ISO 14971
  - Moderation of risk-management meetings
- Human Factors
  - Usability engineering and local support for US or EU handling studies
- Clinical Development
  - Creation of clinical evaluation according to MEDDEV. 2.7.1 by qualified individuals
  - Identification and analysis of relevant clinical data
  - Clinical Investigations


ANTERIS
let's connect!

let's support

100% passion from the beginning

anteris has been founded in 2014 and supports the pharmaceutical, biotech, and medical device industries globally by managing the development of combination products (drug/device and biologic/device combination products; typically EU & US registrations (under 505(j), 505(b)(2), or 351(k) BLA)), medical device products or in vitro diagnostics (Class I, II and III with the goal of CE marking or 510(k) clearance). Our broad competencies cover compliance, regulatory affairs combined with innovative, resource-efficient solutions for compliant technical documentation as well as marketing and sales expertise.

One team – wide ranging expert know-how

We are life sciences and engineering majors with dozens of years of experience in CE marking, 510(k) submissions, and quality systems regulations in all major markets. We are passionate to support our customers wherever they need us at their product lifecycle processes.

Bavarian spirit all over the world

Based with our Headquarters in Holzkirchen (Bavaria, near Munich) - available wherever needed.
We have a broad customer base in four European countries and the US. Our target group covers global players as well as SMEs and Start UPs.

Three core competences complete our portfolio

anteris has created three business units to bundle different competencies and requirements.
Each division supports the other one with the goal of achieving the best possible result.

anteris MEDICAL – anteris medical supports their customers with their medical device challenges, during development, throughout the registration phase, and beyond.

anteris SYSTEMS – anteris systems provides support with feasibility and verification testing of injection systems in combination with the customer's pharmaceutical product candidate.

anteris DIAGNOSTICS – anteris diagnostics means support for in vitro diagnostic (IVD) medical device product development, and registration in EU and US.

let's help

Medical Device support meeting your needs

Product Development means continuing improvement through the entire product lifecycle. No matter at what stage of development you product is, anteris offers individual and customized consulting packages matching exactly your needs. Whether for combination products (medical), In Vitro Diagnostics (diagnostics) or analytical services (systems).

Therefore we focus on effective project management establishing and maintaining compliance with ISO 13485 and 21 CFR 820.

- Concept
- Design
- Design Control
- Risk Management
- Human Factors
- Clinical Development

- Design transfer of development specifications into production and QC specifications
- Project management for upscale projects
- Commercial production
- CMO selection and control (audits)

- Audit
- Marketing and Sales
- Service and Customer Feedback
- PMS
- Design Change Projects
- Documentation maintenance

We ain't satisfied until you are

YOUR BENEFITS:

- A broad network of partners in engineering, clinical development, and manufacturing.
- Providing resources with relevant background.
- Independence, and full focus on medical device regulations and requirements.
- Flexibility with regard to location and timing.
- Integration of anteris resources into customers´ teams.







let’s work

Efficient documentation forms the basis

Building Medical Devices always means managing specifications, risks and tests.
This technical documentation is easily managed by appropriate software tools.
Especially in the field of requirements engineering and documentation it is necessary to hold the DHF documentation always up to date.

Minimal footprint, quick setup

In close cooperation with our partner Matrix Requirements Medical, anteris built two lean but effective software tools to ensure compliant technical documentation and facilitated dossier compilation for combination products as well as IVD products:

TACHYS CP and TACHYS DX.
tachys [Greek] = fast

Learn more about these tools in our separate folders or visit
www.tachys-cp.com

Anyway we are also experienced in the implementation of any other tool available in the market.

let’s play

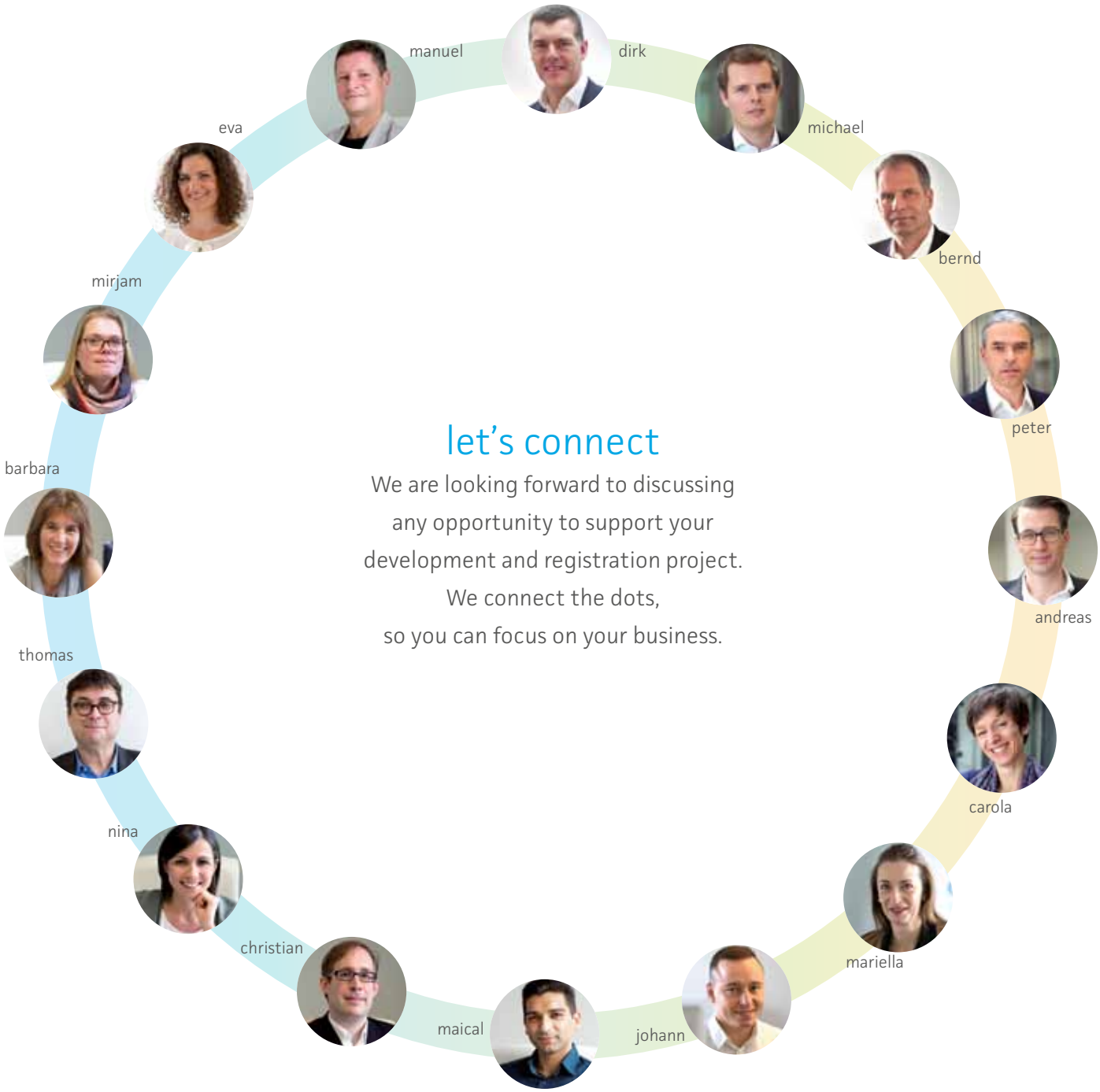
Growing Partner Network – Connecting Competencies

We live and expand partnerships to connect, extend and augment competencies as well as to expand and deepen our knowledge with the aim to ensure the best possible results for our customers.
Our growing network covers at least six topics:

Combination Products	ZEBRASCI COMBINATION PRODUCT EXPERTS · Biopharma Excellence
Consulting	ascendo Professionals · BELLINGSWOOD MEDTECH · ARQon Asia Regulatory & Quality Consultancy Medical Device & Drugs
Supplier	akdd group · MEDIZONE GLOBAL PHARMA SOURCING
Network	Forum MedTech Pharma
Software	Matrix REQUIREMENTS
Research	assay.works

Learn more about our partners at www.anteris-medical/company/partner!

let's connect



let's connect

We are looking forward to discussing
any opportunity to support your
development and registration project.
We connect the dots,
so you can focus on your business.

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