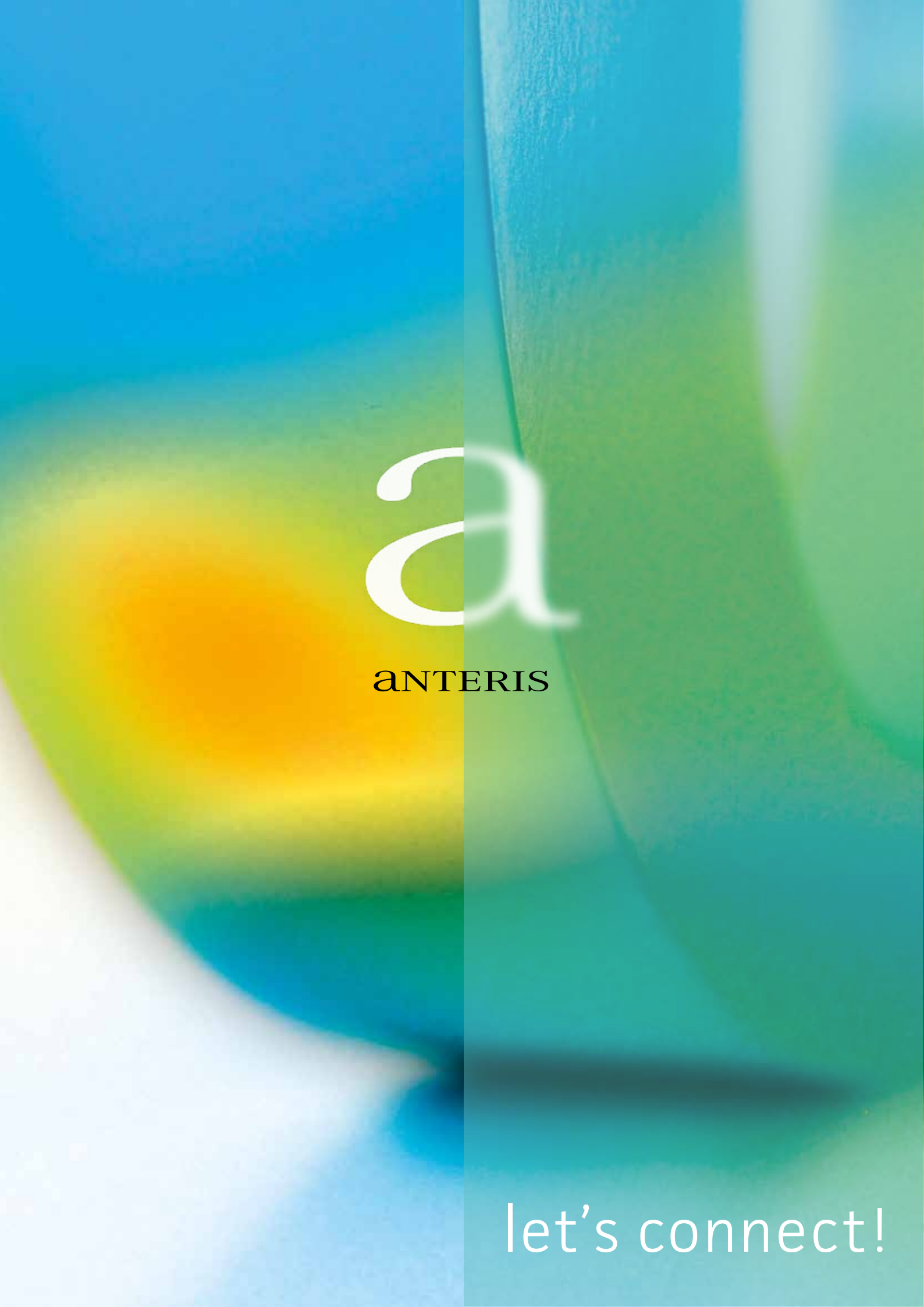

ANTERIS
let's connect!

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

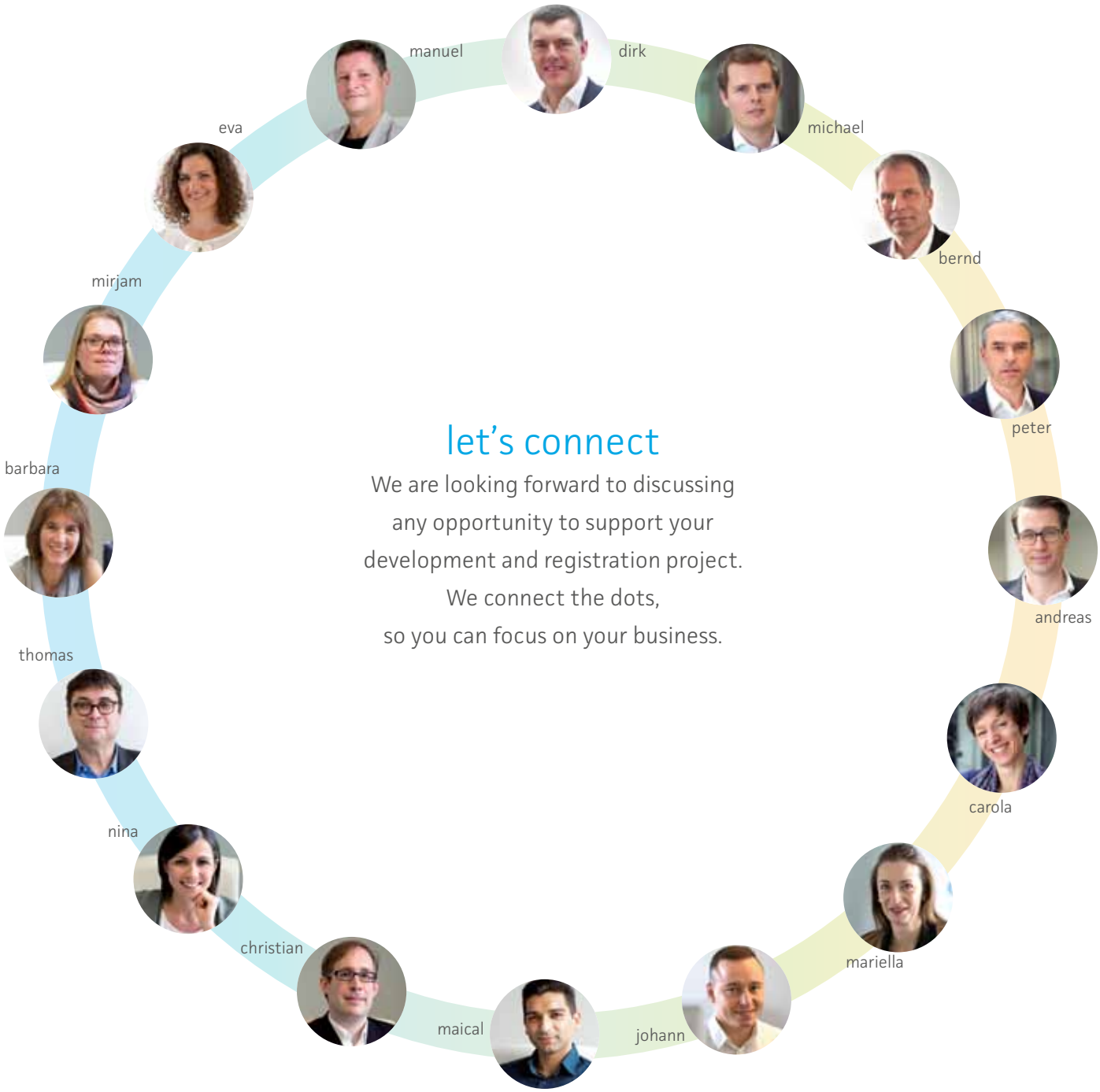
Growing Partner Network – Connecting Competencies

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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anteris [Greek] = support

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