

Quality Accelerator Program

Think. Share. Learn. Apply.

Become the Go-to Expert in Your Company.



September 3-4, 2025



Munich



This is not a traditional conference.

No rhetorical lectures or passive audience.

The focus is set on:

- Interactive engagement
- Adult learning
- Hands-on training
- Dynamic knowledge share
- Strategic problem solving
- Career progression

Through:

- 👥 Workshop formats
 - 💡 Brainstorming sessions
 - 💬 Thought-provoking discussions
- and more...

Welcome to the Accelerator Program.



Session formats



Workshop

In small groups, participants engage in a collaborative session designed to solve a specific problem through structured and practical hands-on activities.



Brainstorming

In small groups, participants generate a wide range of ideas with the goal of producing a diverse set of solutions to a distinct challenge.



Discussion

In a plenary session, participants openly share perspectives on a specific topic by answering a list of questions that will unveil ideas, tips and solutions.



Quality Accelerator Program – Speaker Faculty

NOTIFIED BODIES:



Marta Carnielli
Head of Certification IVD
TÜV SÜD
[LinkedIn](#)



Milad Masjedi
Global Medical Devices
Technical Manager
SGS
[LinkedIn](#)



Rob Laport
IVD Team Lead
DEKRA
[LinkedIn](#)

INDUSTRY:



Bassil Akra
CEO
AKRA TEAM
[LinkedIn](#)



Elem Ayne
President
TEAM PRRC
[LinkedIn](#)



Erik Vollebregt
Partner
AXON LAWYERS
[LinkedIn](#)



Maika Felten
Head of QMS
BIOTRONIK
[LinkedIn](#)



Anna Spehl
Senior Consultant
AKRA TEAM
[LinkedIn](#)



Jenni Ritter
Director Regulatory Affairs
CORPULS
[LinkedIn](#)



Adhiraj Mamak
Sr Manager, Global Quality
Strategy & Alliances
ILLUMINA
[LinkedIn](#)



Muna Kebede
Senior Consultant
AKRA TEAM
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Christian Podolak
VP Quality Management
& Regulatory Affairs
CORPULS
[LinkedIn](#)



Leslie Hammermueller
Senior Consultant
AKRA TEAM
[LinkedIn](#)



Cécile van der Heijden
Attorney-at-Law
AXON LAWYERS
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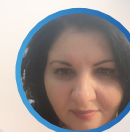
Imene Benachour
Former Business
Development Manager
CELLULOPLAST
[LinkedIn](#)



Philipp Bautz
SCM Master Data
Governance
BIOTRONIK
[LinkedIn](#)



Lawrence Yeh
Quality Manager
Senior Consultant
AKRA TEAM
[LinkedIn](#)



Luminita Tulea
Sr QA/RA Director, Global
QMS Auditing Team
**ADVANCED
STERILIZATION PRODUCTS**
[LinkedIn](#)



Quality Accelerator Program – Pre-event Sessions

PRE-EVENT VOD PRESENTATIONS: Pre-recorded sessions allow for thorough exploration of complex topics that require careful explanation, visual aids, and structured delivery. By covering certain content through VOD, our live sessions can focus entirely on discussion, application, and peer exchange — the elements that truly benefit from real-time participation.

VOD SESSION 1 – EU AI ACT'S DIRECT & INDIRECT IMPACT ON QMS

- Reconciling requirements from the Act & MDR/IVDR
- Integrating the EU AI Act risk assessment framework in the QMS
- Including enhanced transparency & documentation in the TD
- Considerations in designing a roadmap for QMS updates

Cécile van der Heijden, Attorney-at-Law – **AXON LAWYERS**

VOD SESSION 2 – THE 2025 PRRC : ENSURING A WELL-DEFINED ROLE & INTEGRATION IN THE QMS

- Updating the scope of the PRRC's role & inclusion in:
 - Technical documentation
 - Quality management system
- Management Representative per ISO 13485 versus PRRC
- Ongoing points to clarify with responsibilities & liability
- Learnings from recent years & outlook into the future PRRC role

Elem Ayne, President – **TEAM PRRC**

VOD SESSION 3 – METHODS TO ENHANCE QUALITY CONTROL FROM THE IMPORTER/DISTRIBUTOR'S PERSPECTIVE

- Back to the basics: Keys to ensure a solid relationship
- Enhancing visibility, control & management of the EO
- Practical insight from the EO to avoid common pitfalls

Imene Benachour, Former Business Development Manager – **CELLULOPLAST**



Quality Accelerator Program – Agenda September 3, 2025

8:00 | REGISTRATION & WELCOME COFFEE

8:30 | OPENING REMARKS

8:45 | KICK STARTER

Let's break the ice by taking a moment to get to know each other and make new connections. Be ready to share something interesting about yourself!

9:00 | KEYNOTE ADDRESS – REGULATORY CHECK-UP: RECENT UPDATES & EXPECTED CHANGES IMPACTING DEVICE & IVD QUALITY TEAMS

With the goal of remaining at the forefront of continuously evolving regulatory and quality requirements, this session will kick off the program by walking us through recent developments affecting quality processes; as well as what can be expected with the European Commission's evaluation of both regulations and how to prepare accordingly.

[Bassil Akra, CEO - AKRA TEAM](#)

9:40 | COFFEE & NETWORKING

10:00 | WORKSHOP – FOCUS ON ARTICLE 10a & CRITICAL UPDATES TO THE QMS

- Outline of legal obligations & gap analysis
- Impact on each type of Economic Operator
- Structuring the process:
 - Market evaluation
 - Drafting procedures
 - Achieving a LEAN & compliant strategy

[Bassil Akra, CEO - AKRA TEAM](#)

[Erik Vollebregt, Partner - AXON LAWYERS](#)

[Lawrence Yeh, Quality Manager & Sr Consultant - AKRA TEAM](#)

11:30 | DISCUSSION – UNVEILING MULTIFACTORIAL BENEFITS OF A LIFECYCLE APPROACH TO THE QMS

Shift the QMS process mapping to focus on a product lifecycle perspective, ensuring critical points are proactively foreseen & integrated, inputs/outputs are clearly defined, timelines and costs are realistic, and compliance is optimized throughout the entire system.

[Luminita Tulea, Sr QA/RA Director, Global QMS Auditing Team - ASP](#)

12:15 | LEARNING INTERLUDE

12:30 | LUNCH & NETWORKING

1:30 | BRAINSTORMING – GETTING THE BASICS RIGHT: KEY POINTS IN THE INVOLVEMENT OF QUALITY TEAMS IN R&D PROCESSES

- Common pitfalls in team collaborations & how to avoid them
- Critical considerations for:
 - New product design & development
 - Updates on existing products & change control management
- Identifying & organizing interdependencies in the system

[Anna Spehl, Sr Consultant - AKRA TEAM](#)



Quality Accelerator Program – Agenda September 3, 2025

2:30 | BRAINSTORMING – UNIFYING QUALITY & OPERATIONAL EXCELLENCE

While QM processes focus on compliance, operational teams prioritize efficiency, and this disconnect creates parallel systems that do not fully support each other. However, integrating both needs into a single, cohesive system can leverage the full power of business process management to create a unified approach that serves both quality and operational demands.

- Proven building blocks for successful integration
- Effective organizational structures
- Modern methodologies to simultaneously satisfy:
 - Compliance requirements
 - Efficiency goals
- Optimizing costs throughout quality & operations

Maika Felten, Head of QMS – **BIOTRONIK**

Philipp Bautz, SCM Master Data Governance – **BIOTRONIK**

3:30 | COFFEE & NETWORKING

4:00 | DISCUSSION – RE-THINKING QUALITY & TAKING THE ROLE TO THE NEXT LEVEL

In cost-cutting times, how can the quality function be repositioned to the overarching, foundational backbone of a system that could not operate otherwise? What does a quality culture mean, realistically? What defines the quality role to its full extent, and which personal and professional traits should be sought after? How can the role be more productive, proactive, efficient yet fulfilling? This interactive discussion will explore and define solutions to ensure all gaps

are filled for the quality role to be well recognized and considered internally, moving far beyond just complying with requirements.

Adhiraj Mamak, Sr Manager, Global Quality Strategy & Alliances
ILLUMINA

4:45 | QMS DIGITIZATION: FROM IMPLEMENTATION TO PROCESS ADVANCEMENT

Join groups categorized by level of experience and advancement in the digitization of QMS to share questions, challenges and solutions about accurately organizing, maintaining and continuously improving QMS strategies and relevant documentation.

GROUP 1 – BEGINNER: Defining needs & opportunities

GROUP 2 – INTERMEDIATE: Key implementation steps

GROUP 3 – ADVANCED: Continuous optimization

5:30 | LEARNING INTERLUDE

5:45 | CLOSING REMARKS

7:00 | OPTIONAL GROUP DINNER

Participants who wish to gather with fellow attendees for continued networking, conversation and simply a pleasant moment in the city are welcome to join us at a select restaurant (individual payment).



Quality Accelerator Program – Agenda September 4, 2025

8:00 | WELCOME COFFEE

8:20 | OPENING REMARKS

8:30 | WORKSHOP – FOCUS ON ENHANCING IN-HOUSE QUALITY SYSTEM AUDIT READINESS

- Methods to best plan & structure internal audits
- Optimizing the use of MDCG guidance & more
- Analyzing key findings & setting actionable solutions

Christian Podolak, VP Quality Management & Regulatory Affairs
CORPULS

Jenni Ritter, Director Regulatory Affairs – **CORPULS**

10:00 | COFFEE & NETWORKING

10:30 | DISCUSSION – WHERE QUALITY MEETS CLINICAL: EFFICIENTLY HANDLING TEAM INTERDEPENDENCIES

- Interrelationship of clinical processes within the QMS
- Properly addressing clinical in the QMS per ISO 14155
- Closing clinical-related gaps in the overall QMS
- Oversight of incident & event reporting structures

Leslie Hammermueller, Sr Consultant – **AKRA TEAM**

Lawrence Yeh, Quality Manager & Sr Consultant – **AKRA TEAM**

11:15 | DISCUSSION – LET’S TALK: UNRESERVED PERSPECTIVES FROM NOTIFIED BODIES

This is the opportunity to have open, honest and candid conversations with notified bodies during the program. Questions pertaining to specific areas of scrutiny in QMSs, common triggers when reviewing technical files or performing audits and more will be submitted by participants prior to the session as well as fielded live, enabling timely and invaluable insight to be shared.

Marta Carnielli, Head of Certification IVD – **TÜV SÜD**

Milad Masjedi, Global Medical Devices Technical Manager – **SGS**

Rob Laport, IVD Team Lead – **DEKRA**

12:15 | LEARNING INTERLUDE

12:30 | LUNCH & NETWORKING

1:30 | WORKSHOP – SOLIDIFYING & STREAMLINING NON-CONFORMITY MANAGEMENT

- Identify QMS weaknesses in non-conformity management
- Addressing non-conformities raised from:
 - Outside bodies
 - Audits by authorities
- Change management & CAPA efficiencies

Muna Kebede, Senior Consultant – **AKRA TEAM**

Cécile van der Heijden, Attorney-at-Law – **AXON LAWYERS**



Quality Accelerator Program – Agenda **September 4, 2025**

2:45 | DISCUSSION – CAPA MANAGEMENT: OVERCOMING COMMON OBSTACLES TO AN OPTIMAL SYSTEM

- Upgrade of the root-cause analysis process
- Ensuring realistically applicable preventive actions
- Interdisciplinary approach & multi-team involvement
- Advocating for further investment in CAPA

Rob Laport, IVD Team Lead – **DEKRA**

3:30 | FINAL LEARNING INTERLUDE & TAKEAWAY TIME

3:45 | PROGRAM CLOSING



Quality Accelerator Program

WHO SHOULD ATTEND:

- All quality-related and/or regulatory professionals
- Specialists to Executive level
- PPRCs
- Small to large medical device and/or diagnostic manufacturing companies
- Notified body representatives
- Competent Authority representatives

ACTIVATING THE POWER OF STRATEGIC NETWORKING

- **Connection catalyst:** Instead of getting lost in a large pool of participants, our human-scale program enables direct engagement between peers who focus on similar challenges and directly learn from each other.
- **Professional community building:** Create a supportive network of like-minded professionals who can serve as future resources, mentors, and problem-solving partners.
- **Cross-organizational learning:** Engage with professionals from diverse companies and backgrounds, gaining perspectives that challenge and expand your current approaches to quality management.

WHY ACTIVE LEARNING TRANSFORMS PROFESSIONAL DEVELOPMENT

- **Engagement drives retention:** Adults learn best through active participation, with research showing up to 75% higher knowledge retention compared to passive listening.
- **Practical application:** Hands-on learning bridges the critical gap between theoretical knowledge and realworld implementation, enabling immediate skill transfer.
- **Collaborative insight:** Interactive workshops foster peer-to-peer learning, allowing professionals to leverage collective expertise and diverse perspectives.
- **Skill mastery:** By doing, not just hearing, participants develop deeper understanding and muscle memory for complex quality management techniques.





Looking forward to meeting you!

Do you have questions?

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Alexia Lynch

Training and Community Engagement Lead

AKRA TEAM

