6th Qserve MedTech Conference 2026

November 10-12, 2026

Amsterdam, The Netherlands

qservegroup.com/qserve-conference

Ready for the Next Regulatory Era—Where Connections Matter

Bringing together the brightest minds in regulatory affairs, quality, and clinical to help you stay ahead in an ever-evolving landscape.

training@qservegroup.com

PROGRAMME

PROGRAMME · DAY 1

10 November 2026

8:00 – 9:00 CET

REGISTRATION

09:00 - 12:30 CET

Training I - From Potential to Strategy: Unlocking Real-World Data for MedTech & IVD Success

Real-world data (RWD) is rapidly reshaping how MedTech and IVD companies generate clinical evidence and demonstrate value. But without a clear strategy, RWD initiatives often fall short of regulatory and business expectations. This half-day workshop focuses on building a robust, future-proof RWD strategy aligned with regulatory requirements and organizational goals. You will explore how to position RWD within your clinical, regulatory, and market access strategies, and how to determine when and where it adds the most value.

Bianca Lutters
Regulatory & Clinical Expert

09:00 - 12:30 CET

Training II - From Concept to Compliance: Mastering Design Controls, Intended Purpose & eQMS

This half-day workshop combines three critical elements, design controls, intended purpose and claims, and the implementation of an electronic Quality Management System (eQMS). You will learn how to define intended purpose and indications for use in a way that supports regulatory strategy and avoids costly delays. The session also covers how to structure design control processes in line with regulatory expectations, and how an eQMS can streamline documentation, traceability, and collaboration.

Robert Paassen
Start-Up Lead

Jorn van Binsbergen
Regulatory & Clinical Expert

09:00 - 12:30 CET

Training III - Agile Meets Compliance: Building Regulatory-Ready Software for MedTech (part I)

Agile methodologies promise speed, adaptability, and continuous improvement, but how do you apply them in a highly regulated MedTech environment without compromising compliance? This full-day interactive session bridges the gap between Agile principles and regulatory expectations for medical device and IVD software development. You will explore how to align Agile workflows with standards such as IEC 62304, ISO 13485, and evolving regulatory frameworks, while maintaining traceability, documentation, and risk control.

Coenraad Davidsdochter
Regulatory & Clinical Expert

09:00 - 12:30 CET

Training IIII - Choosing the Right FDA Regulatory Pathway

Selecting the appropriate FDA regulatory pathway is one of the most critical strategic decisions for medical device manufacturers entering the US market. This half-day workshop provides a practical guide to understanding and navigating FDA pathways, including pre-submissions, 510(k), IDE, PMA, Humanitarian Device Exemption (HDE), and Breakthrough Device Designation. You will learn how to develop an effective FDA regulatory strategy, evaluate device characteristics, risk classification, predicate availability, and clinical evidence requirements to determine the most suitable regulatory route.

Lorry Weaver
Principal Consultant

Inette Nieveen
Chief Operating Officer

PROGRAMME · DAY 1

10 November 2026

12:30 - 13:30 CET

Networking Lunch

13:30 - 17:00 CET

Training I - From Data to Evidence: Implementing Real-World Data for PMCF & Registries

Real-world data (RWD) is becoming a cornerstone of clinical and regulatory strategies in MedTech. This half-day workshop focuses on the practical implementation of RWD for Post-Market Clinical Follow-up (PMCF) and registry-based studies. You will learn how to design, collect, and use real-world data to generate meaningful clinical evidence that meets regulatory expectations. The session covers data sources, study design, governance, and integration into your clinical and regulatory strategy.

Jorn van Binsbergen
Regulatory & Clinical Expert

Wouter Mattheussens
Clinical Project Manager

13:30 - 17:00 CET

Training II - Biocompatibility in Practice: Navigating the updates of ISO 10993-1:2025

With the latest updates to ISO 10993-1:2025, biocompatibility evaluation continues to evolve, requiring a more risk-based and strategic approach. This half-day workshop provides a clear and practical overview of the new requirements and their impact on medical device development. You will learn how to plan, assess, and document biocompatibility in line with the updated standard, including when testing is required and when a justification-based approach is sufficient.

Bianca Lutters
Regulatory & Clinical Expert

13:30 - 17:00 CET

Training III - Agile Meets Compliance: Building Regulatory-Ready Software for MedTech (part 2)

Agile methodologies promise speed, adaptability, and continuous improvement, but how do you apply them in a highly regulated MedTech environment without compromising compliance? This full-day interactive session bridges the gap between Agile principles and regulatory expectations for medical device and IVD software development. You will explore how to align Agile workflows with standards such as IEC 62304, ISO 13485, and evolving regulatory frameworks, while maintaining traceability, documentation, and risk control.

Coenraad Davidsdochter
Regulatory & Clinical Expert

13:30 - 17:00 CET

Training IIII - Securing MedTech Innovation: Practical Approach for Breakthrough Devices in the EU and USA

Bringing breakthrough medical technologies to market demands a clear regulatory strategy. This half-day workshop provides a practical overview of the regulatory pathways, strategic considerations, and best practices for accelerating breakthrough medical devices in both the EU and the USA. You will learn how to define an innovation strategy, navigate evolving regulatory frameworks, engage effectively with regulatory authorities, and build evidence packages that support market access. Avoid common pitfalls, and develop a roadmap for successfully bringing innovative medical devices to patients.

Lorry Weaver
Principal Consultant

Robert Paassen
Start-Up Lead

PROGRAM · DAY 2

11 November 2026

7.30 – 9.00 CET

REGISTRATION

09:00 - 10:00 CET

Plenary Welcome - Navigating Change: The Big Picture for Medical Devices in Europe

The European medical device landscape is changing rapidly. From the implementation of the MDR and IVDR to the evolving regulatory framework for digital and AI-enabled devices, manufacturers, clinical teams and regulatory professionals are navigating a growing number of challenges and opportunities. This plenary welcome session brings together speakers from across the conference program to explore the bigger picture behind the topics. Through an open conversation around six key themes, our speakers will connect the dots between regulatory developments, clinical evidence, quality systems and emerging technologies, discussing what the latest changes mean in practice. The panel will focus on the questions that matter most to the medical device community: What is changing? Where are the biggest uncertainties? How should organizations prepare? And where can greater engagement between industry, clinical experts and regulators help move the field forward?

Moderator: Gert Bos (Qserve)

10:00 - 10:45 CET

In-Depth MDR

The MDR continues to evolve, but for manufacturers the key question remains: what does it mean in practice? This in-depth session brings together regulatory experts and specialists to examine the current state of MDR implementation, the challenges manufacturers are facing, and the developments that are likely to shape the regulatory landscape ahead. The session closes with a Q&A focused on the questions that matter most in day-to-day MDR implementation.

In-Depth IVDR

The IVDR has fundamentally changed the regulatory landscape for in vitro diagnostics, but the transition from requirements on paper to implementation in practice presents significant challenges. This in-depth session brings together experts from the IVD ecosystem to discuss challenges, lessons learned, and how to prepare for the next phase of IVDR implementation. The session concludes with a Q&A.

10:45 - 11:00 CET

Coffee and Tea Break

11.00 - 12.30 CET

STREAMS

Digital Health

AI in Medical Devices: Practical guidance for ensuring Regulatory Compliance and Impact on Submissions

This session provides a clear overview of how AI-driven devices are regulated under MDR, IVDR, and upcoming guidance. You will explore how AI impacts clinical evaluation, risk management, and submission documentation, including unique considerations for adaptive algorithms and software updates.

Speakers: Coenraad Davidsdochter (Qserve) & Malte Knowles-Schmidt (TÜV SÜD) & Beatrice Federici (TU Eindhoven)

General & Start-Ups

QMS that Works: Building Systems that Truly Add Value

This session focuses on building and maintaining a A Quality Management System (QMS) that drives efficiency, compliance, and continuous improvement. Learn how to move beyond "check-the-box" compliance, and create a system that supports your teams and business goals.

Speakers: Francois Naye (Qserve) Gunnar Ulrich (DNV) & Frédéric Daval (Kinetec)

IVD

IVDR Readiness: How Prepared Are You Really?

In this session, we'll focus on IVDR compliance from the perspective of large manufacturers, SMEs and start-ups as well as Notified Bodies. We'll help you assess your IVDR compliance and identify gaps by highlighting key IVDR requirements, and exploring effective strategies.

Speakers: Kristiane Schmidt (Qserve) & Molly Rogers (DNV)

Clinical

High-Risk Clinical Investigations: Lessons from Clinical Trials

This session shares real-world experience from a novel heart valve case. Dive into high-risk clinical investigation requirements and discover key challenges and solutions. Identify success factors and learn from real case experience.

Speakers: Wouter Mattheussens (Qserve), Sara Haimanot (Dekra) & Wiebe Postma (BVI)

12:30 - 14:00 CET

Networking Lunch

14:00 - 15:30 CET

STREAMS

Digital Health

Digital Omnibuses: Navigating through the Transforming Landscape

This session provides a practical overview of regulatory, technical, and clinical considerations for digital health products. You will learn about interoperability, cloud-based solutions, data exchange, and integration of digital technologies into health ecosystems.

Speakers: Coenraad Davidsdochter (Qserve) & Cecile van der Heijden (Axon Lawyers)

General & Start-Ups

Engaging with Regulators: How to Maximize Value from Interactions MDR versus FDA

This session provides practical guidance on how to prepare for and manage interactions with regulators and Notified Bodies. Learn how to ask the right questions, present your case clearly, and build constructive relationships. with regulatory authorities to impact your success.

Speakers: Gert Bos (Qserve), Lorry Weaver (Qserve), Malte Knowles-Smidt (TÜV SÜD), Diego Faletti (BSI) & Daan Pelgrom (DEKRA)

IVD

Companion Diagnostics (CDx): Submission Lessons Learned

Companion diagnostics present unique regulatory challenges. This session explores lessons learned from CDx submissions and how to navigate them successfully.

Speakers: Daphne Smit (Qserve), Maurice Steenhuis (CCMO) & Julie Mutert (CellCarta)

Clinical

Clinical Evaluation for Software & AI Devices

Clinical evaluation for software and AI devices requires a tailored approach. This session provides practical guidance on demonstrating clinical performance and safety.

Speakers: Jorn van Binsbergen (Qserve), Yun-Hsuan Chang (Scarlet) & Floor van Leeuwen (IQMessenger)

15:30 - 16:00 CET

Coffee and Tea Break

16:00 - 16:30 CET

Plenary Closing

How do the different conversations of the day come together, and what should we take forward? In this closing plenary, Qserve track leads will share the key takeaways, insights and open questions from across the conference programme. The focus will be on the bigger picture: What stood out? What has changed? Where are the biggest challenges and opportunities? And what should the medical device community be thinking about next? The final part of the session will be an open mic for the audience. This is your opportunity to share a final thought, raise another question, challenge a perspective, or highlight an issue that deserves further discussion. Join us as we connect the dots across the different tracks, reflect on the key messages from the conference, and look ahead to the conversations that still need to happen.

Moderator: Gert Bos (Qserve)

16:30 - 17:15 CET

Demo

Demo AI Clinical

Our Clinical team will show you how we use AI to make part of our clinical services more efficient, while maintaining compliance.

Demo Qserve InSight

Our Regulatory Intelligence experts will guide you through our InSight platform and address any questions you may have.

Demo Qserve Learn

Our Learn experts will tell you everything you need to know about our dedicated training platform for the MedTech and IVD Sectors.

16:00 - 16:30 CET

Dinner & Evening Program

PROGRAM · DAY 3

12 November 2026

09:00 - 09:30 CET

REGISTRATION

09:15 - 10:00 CET

Plenary Session - Regulatory Science & Intelligence in an AI-Supported World

Artificial intelligence is rapidly becoming part of the way medical devices are developed, assessed, regulated and used. But what happens when AI starts supporting the people and organizations responsible for making regulatory decisions? This session explores how AI is reshaping regulatory science and regulatory intelligence across the medical device ecosystem. From conformity assessment and quality management to hospital care and the work of consultants and CROs, our speakers will share how AI is already being used, where it can create value, and where new questions and risks emerge.

These perspectives will then come together in a panel discussion around two key themes, exploring both the opportunities and the practical and regulatory challenges of an AI-supported regulatory environment.

Moderator: Gert Bos (Qserve)

10:00 - 11:30 CET

STREAMS

Digital Health

Software, AI and Risk Management: Compliance in Action

This session explores software lifecycle management, risk management integration, and compliance with IEC 62304 and ISO 14971. You will gain practical guidance on documenting software development, validation, and risk mitigation while maintaining regulatory compliance.

Speakers: Cornelia Luban (Qserve), Dr. Andrei Ninu (DQS) & Stefan Leitenberger (Philips)

General & Start-Ups

Start-Up Survival Guide: Overcoming Regulatory Challenges - Europe versus USA

This session focuses on the most common regulatory challenges start-ups face, and provides practical solutions to overcome them efficiently. Learn how to prioritize resources, build a scalable regulatory strategy, and avoid costly mistakes.

Speakers: Robert Paassen (Qserve), Lorry Weaver (Qserve), Matthias Bellmann (TÜV SÜD) & Daniele Zanotti (StartTric)

Global Registrations

The PRRC Role: Responsibilities, Challenges & Ethics

This session explores responsibilities, challenges, and ethical considerations for the Person Responsible for Regulatory Compliance (PRRC) role. As a PRRC, you are accountable for ensuring compliance with EU MDR and IVDR across all aspects of the device lifecycle, including technical documentation, quality management, clinical evidence, and post-market surveillance.

Speakers: René Schings (Qserve)

Clinical

Turning Real-World Data into a Regulatory Asset

This session focuses on how to design efficient, low-burden PMCF strategies that deliver meaningful clinical evidence while staying compliant with MDR and IVDR requirements. Learn how to leverage existing data sources such as PMS data, complaints, literature, and registries, and how to integrate PMCF activities into routine processes.

Speakers: Bianca Lutters (Qserve) & Marcus Torr (Purdie Pascoe)

11:30-13:00 CET

STREAMS

Digital Health

Cybersecurity in Medical Devices: To a Safer Reality in Healthcare

This session provides a practical overview of how to implement cybersecurity across the product lifecycle, aligned with MDR, IVDR, and international guidance. Learn how to identify vulnerabilities, manage threats, and ensure secure design, while maintaining compliance.

Speakers: Mike Szymonik (Qserve), Steven Byrne (Scarlet)

General & Start-Ups

Clinical Challenges for Start-Ups: From Evidence to Approval

This session explores practical strategies for start-ups to design and execute clinical activities efficiently. Learn more about clinical requirements and how to develop a clinical strategy that aligns with regulatory requirements while managing limited resources.

Speakers: Robert Paassen (Qserve), Bianca Lutters (Qserve), Richard Holborrow (BSI) & Daniele Zanotti (StarTric)

Global Registrations

Regulatory Intelligence: Staying Ahead Without Overload

This session helps you build an efficient regulatory intelligence system without getting overwhelmed by all regulatory information that is constantly evolving. Learn about Regulatory Intelligence fundamentals, sources, tools, filtering, prioritization and implementation strategies.

Speakers: Dennis Sarwin (Qserve) & Adelina Chiaravalloti (Corcym)

Clinical

PMCF Surveys – Minimum effort, Maximum output!

This session focuses on designing and implementing effective surveys, focusing on Post-Market Clinical Follow-Up Surveys as a key tool for real-world data collection. Understand survey design principles, identify common pitfalls and learn how to collect high-quality data,

Speakers: Wouter Mattheussens (Qserve), Richard Holborrow (BSI) & Martin Stofanko (Adaptix)

13:00 - 14:00 CET

Networking Lunch with Activity

14:00 - 15:30 CET

STREAMS

Digital Health

Navigating Europe's Digital Health Regulations: EHDS, GDPR & Beyond

This session provides a practical overview of how Europe's digital health regulations interact and what it means for your company. Learn how to ensure compliance with data protection requirements while leveraging opportunities for innovation, including secondary use of health data and real-world evidence.

Speakers: Mike Szymonik (Qserve) & Floor van Leeuwen (IQMessenger)

General & Start-Ups

Submission Success: Lessons Learned from Real Cases

This session shares real-world experiences and lessons learned from regulatory submissions, highlighting common mistakes and best practices. You will gain practical insights into how to build a compliant and effective submission file.

Speakers: Bianca Lutters (Qserve), Diego Faletti (BSI), Marx Bernd (Vygon) & Manfred Lubberich (ProMDService)

Global Registrations

EUDAMED Bulk upload: Practical Use and Implementation

This session provides a practical overview of EUDAMED, including a closer look at its different modules. Explore common implementation challenges, practical solutions and useful tips to help you understand EUDAMED's structure and develop an effective implementation strategy to maintain compliant.

Speakers: Dennis Sarwin (Qserve) & Adelina Chiaravalloti (Corcym)

Clinical

Closing the Loop: PMS, PMCF, Risk Management & Clinical Evaluation

This session explains how to align post-market surveillance, PMCF, risk management, and clinical evaluation efficiently by sharing PMS and PMCF overviews and clinical evaluation updates. Learn how to integrate processes and to identify best practices.

Speakers: Jorn van Binsbergen (Qserve), Inge Willems (DEKRA), Daphne Zwartjes (TSC-Life) & Albina Torre (Haleon)

15:30 - 16:30 CET

Plenary Closing Panel

The regulatory landscape is changing, but not every change can be predicted. For manufacturers and other stakeholders in the medical device ecosystem, being ready for the next phase means more than responding to new requirements as they emerge. It means building the ability to anticipate, adapt and make informed decisions in conditions of uncertainty. The panel will focus on a central question: how do you prepare effectively when you do not yet know exactly what the future will look like?

The panel discussion will explore how organizations can build regulatory resilience, identify signals of change early, prepare for different scenarios, and balance immediate compliance priorities with longer-term strategic decisions. It will also consider where organizations should invest now, where flexibility is essential, and how collaboration across the regulatory and medical device community can help navigate uncertainty.

The session closes with a final Q&A, followed by questions to the audience, inviting participants to reflect on their own readiness and share what they believe will be the biggest challenge, opportunity or change in the next phase. End the conference by looking beyond the current regulatory landscape and asking not only what comes next, but how we can be ready for it.

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Hope to See You in Amsterdam!