OVERVIEW VAN R. DE VROEGE

**Training**

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| Good clinical practice-WMO, Den Haag | 05-11-'14 |
| Dekra training, Pedro Eerdmans, Nieuwegein | 03-10-'17 |
| Clinical Evaluation for Medical Devices, BSI Training Academy Course, Den Bosch | 02-11-'17 |
| Privacy, E-learning, Haga Academy | 04-05-'18 |
| Focus on peer review, online course, Nature masterclasses | 17-05-'18 |
| Mini course "MDR 2017/745", easy medical device (cert.) (14, 15, 16, 17, 18, 19/8) | 19-08-'18 |
| GCP, GCP central, online | 31-10-'18 |
| EMWO, Herregistratie | 31-10-'18 |
| Privacybescherming en informatiebeveiliging Zorgverlener, E-learning, Haga Leerplein | 19-12-'18 |
| Awareness Medische apparatuur, E-expert, Haga Academy | 11-03-'19 |

**Webinar**

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|---|---|
| Med Dev Clin Eva and PMS for biom searching, Webinar, Elsevier | 24-02-'16 |
| Language tips for academic writing, Webinar, Wolters Kluwer | 28-04-'16 |
| FDA Biological Evaluation Guidance Webinar, Namsa | 21-06-'16 |
| Post Marketing Surveillance (S522) | 28-06-'16 |
| An update on FDA's Medical Device Clinical Trials program, FDA | 07-07-'16 |
| Next Gen. Seq(NGS) Draft Guidances: Techn and Reg Aspects, FDA | 27-07-'16 |
| Regulatory overview for invest. and spons. of Neu, Webinar, FDA | 14-09-'16 |
| Europe's New Medical Device Regulations (MDR), Webinar, Emergo | 29-09-'16 |
| Postmarket managm. of cybersecurity in med. dev, Webinar, FDA | 12-01-'17 |
| Xtra, autotransfusion equipment, LivaNova (2013) | 13-01-'17 |
| Cardiohelp, Maquet | 17-01-'17 |
| Precision Medicine: Learning Lessons From the Microbiome, Webinar, The Scientist | 31-01-'17 |
| Clinical Evaluation Reports (CERs): Global Benefits & The Impact of MEDDEV Updates to Manufacturers Webinar, Namsa | 08-02-'17 |
| Factors to Consider Regarding Benefit-Risk in Medical Device Product Avail, Compl, and Enforcement Dec, Webinar, FDA | 09-02-'17 |
| Designing an Effective Clinical Trial, Web, Namsa | 07-03-'17 |
| How to Improve the Speed and Effic. of Your Clin Trials, Web, Cmed | 28-03-'17 |
| Risk Management for Medical Device Manufacturers, Part 1 Overview of Risk: Is risk really as simple as it seems? Web, Qmed | 28-03-'17 |
| Bioskills and its Role in Product Development, Web, Namsa | 29-03-'17 |
| Part 2 Mechanics of Risk: What do we do with this information?Web, Qmed | 29-03-'17 |
| Part 3 Advanced Topics in Risk: What are best practices and how do we avoid problems? Web, Qmed | 28-03-'17 |
| The Benif of Utilizing a Contract FCE in Clinical Trials, Web, Namsa | 11-04-'17 |
| Clinical Trial Considerations in Cerebral Protection for TAVR Patients, Web, Novella | 26-04-'17 |
| PMS & PMCF under the European MDR, Web, Emergo | 17-05-'17 |
| EU IVD Regulation: Top Five Changes for Med Dev Man to Consider, Web, Namsa | 25-05-'17 |

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| Choosing the Right Partner to Build a Successful Direct-to-Patient (DTP) Clinical Trial Framework, Web, Sharp | 05-06-'17 |
| Developing a Biological Safety Evaluation, (April 18, 2017), Web, Nelson Labs | 13-06-'17 |
| Overview of regulatory requirements; Medical Devices', Web, FDA | 27-06-'17 |
| Inspections - Global Harmon, Guidance on the content of quality management system audit reports GD211 training (5 modules), Web, FDA | 27-06-'17 |
| Distinguishing Medical Device Recalls from Medical Device Enhan Cements, Web, FDA | 28-06-'17 |
| Introduction to Medical Device Recalls: Industry Responsibilities, Web, FDA | 28-06-'17 |
| Medical device desinfection for reprocessing products for US and EU, Nelson lab (Qmed) | 07-07-'17 |
| The new Medical Device regulations, Webinar, TUV Sud (RF) | 12-07-'17 |
| Risk-Based Thinking in your Operations – Tools and tips for incurporating Risk,into Quality Management, Web seminar, ETQ | 13-07-'17 |
| Getting 510(k) clearance for your device from the US FDA, Webinar, Emergo | 13-07-'17 |
| Data Integrity and the Manufacturing Control Strategy for Life Sciences Manufacturers, Webinar, Werum | 19-07-'17 |
| Understanding Medical Device Regulatory Pathways in China and Japan, Webinar, Namsa | 20-07-'17 |
| Fundamentals of Risk Management, Web seminar, Dekra | 27-07-'17 |
| Medical device cybersecurity, Webinar, Emergo | 10-08-'17 |
| Qualification of Medical Device Development Tools, Web, FDA | 24-08-'17 |
| Medical Devices: Reviewing Regulatory Changes in the US and EU-Broadcast #1, Web, INC | 24-08-'17 |
| Risk Management according to EN ISO 14971:2012: a strategic Approach. Webinar, Emergo | 27-09-'17 |
| Developing a Cyber-Security Strategy, Webinar, TUV Sud (RF) | 03-10-'17 |
| EU MDR and Its Impact on Cardiovascular Manufacturers, Webinar, TUV Sud (RF) | 10-10-'17 |
| Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices, Web, FDA | 10-10-'17 |
| Beware the Hidden Costs of Conducting Clinical Trials: Understanding the Landmines and How to Avoid Them, Webinar, MedPace | 11-10-'17 |
| ISO 13485:2016: How to Incorporate Risk-Based Quality Systems that Lead to Efficient Decision Making Webinar, Namsa | 19-10-'17 |
| Clinical Event Adjudication: Comprehensive and Efficient Dossier Review Using a Global On-Line Solution, Webinar, Bioclinica | 26-10-'17 |
| Europe's new Medical Device Regulation (MDR 2017/745) Webinar, Emergo | 26-10-'17 |
| The Agency's recommendations for developing safe and effective devices that exchange and use patient information electronically, Web, FDA | 26-10-'17 |
| Applying Risk-based Thinking in Medical Devices, Webinar, MedTech Intelligence | 31-10-'17 |
| Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies, Web, FDA | 31-10-'17 |
| Building Effective Document Control in an ISO 9001:2015 Quality Management System, Webinar, Quality digest | 07-11-'17 |

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| Unique Device Identification: Direct Marking of Devices Final Guidance, Webinar, FDA | 30-11-'17 |
| Implementing Risk Strategies for the Supply Chain, Webinar, Verse Solutions/ FDA (certificate) | 06-12-'17 |
| AHA Expert Advice: Coding for Advanced Cardiovascular Services: Impella and Heart Assist Devices, Webcast, Abiomed. | 12-12-'17 |
| Business Impact of the new EU Medical Device Regulation – An Executive Briefing, Webinar, LU (late recorded 20-07-'17) | 19-12-'17 |
| Conduct Audit-Ready Literature Reviews for Your CERs: A Systematic Method, Webcast, RAPS (certificate) | 19-12-'17 |
| How to Effectively Communicate with Regulators, Webcast, RAPS (certificate) | 20-12-'17 |
| Case Study - Bringing Agility and Automation to New Drug Appli-Cation, Webcast, RAPS (certificate) | 27-12-'17 |
| 7 Key Questions to Evaluate Your Food Science & Nutrition Infor-mation Webinar, Research Information | 25-01-'18 |
| Are You Ready for the EU's General Data Protection Regulation?, Webinar, TUV Sud (RF) | 13-02-'18 |
| How to Ensure Your Clinical Evaluation Reports (CER) Comply with EU MEDDEV 2.7/1 rev 4. Webinar, Emergo | 21-02-'18 |
| How to Better Manage Quality and Risk with a Global Change Control Strategy, Webcast, RAPS (certificate) | 21-02-'18 |
| How to Use Real-World Evidence to Support Regulatory Decision-Making for Medical Devices, Webinar, Namsa. | 21-02-'18 |
| Simulation & the Digital Twin for Better Medical Device Design, Webinar, (Xtalks) Siemens. | 23-02-'18 |
| Are Stem Cells Ready for Prime Time? A Look at FDA Research Advances in Regenerative Medicine, Webinar, FDA (certificate) | 08-03-'18 |
| Preparing Research Organizations for Digital Tools and Part 11 Combination Product Updates for "Acceptance and Filing Reviews for Premarket Approval Applications" and "Refuse to Accept Policy for 510(k)s", Webinar, FDA. | 20-03-'18 |
| How to Ensure Your Clinical Evaluation Reports (CER) Comply with EU MEDDEV 2.7/1 rev 4. Webinar Emergo | 21-03-'18 |
| Preparing Research Organizations for Digital Tools and Part 11 Compliance, Webinar, Kinetiq. (certificate) | 22-03-'18 |
| ISO 45001: Migration and Integration, Webinar, SAI Global | 22-03-'18 |
| EN ISO 13485 compliance for Europe, Webinar, Emergo | 23-03-'18 |
| Digital Evidence Generation: Simulation and the Digital Twin for Better Medical Device Design, Webinar, (Xtalks) Siemens. | 23-03-'18 |
| How Can Functional Medicine Techniques Enhance Your Practice & PMS related webinars and courses Patient Outcomes". Webinar, Biolife | 27-03-'18 |
| Leveraging Post-Market Surveillance and Clinical Follow-Up Data to Support EU MDR Compliance. Webinar, (Xtalks) Namsa | 27-03-'18 |
| FDA Perspectives on Computer Simulations in the Evaluation of Medical Devices, Webinar, Siemens. | 29-03-'18 |
| Expert Coding Advice: Dr. Z on Advanced Cardiovascular Procedures, Including Impella and Heart Assist Devices, Webinar, Abiomed. (cert) | 05-04-'18 |
| Understanding the Use & Value of Biocompatibility Standards for Medical Devices under ISO 10993-1, Webcast, Namsa | 11-04-'18 |

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| Steps to a Successful Advisory Committee Meeting, Webcast, RAPs (cert) | 11-04-'18 |
| Applying Risk-Based Thinking in the Medical Device Industry, (EtQ) FDA news (cert) | 11-04-'18 |
| Risk Management for Medical Devices in the New Regulatory Environment, Webinar, Emergo | 19-04-'18 |
| China FDA Draft Guidance on Acceptance of Overseas Clinical Trial Data–Understanding the Potential Impact to Med Device Manufacturers, Webcast, Xtalks/Namsa | 20-04-'18 |
| Castor EDC: New features, Webinar, Castor (cer) | 25-04-'18 |
| Understanding and Applying FDA's 510(k) Modifications Guidance, Webcast, RAPs (cert) | 25-04-'18 |
| Prepare Your Site for Challenges in Gene Therapy Research, Webinar, Bio-tronics | 25-04-'18 |
| Clinical Trial Portals Absolutely, Positively Essential for Small, Mid-Size Biotech Firms Are You Standing Out in an Increasingly Crowded Space, Webinar, FDAnews (cert.) | 27-04-'18 |
| IOT (Internet of Things) Innovation in Healthcare, Webcast, Xtalks/AT&T | 30-04-'18 |
| How Digital Technology is Transforming: YOUR Quality Management, Webinar, FDAnews | 01-05-'18 |
| EuroELSO Webinar: Controversies of eCPR, Webinar, ELSO | 02-05-'18 |
| Linking Study Quality to Leading Practices for Proactive Planning, Webinar, Avoca Quality & goBalto | 03-05-'18 |
| How the Internet of Things is Enabling the Medical Device Market, Webcast, Xtalks/Terso | 08-05-'18 |
| FDA's Predictive Toxicology Roadmap: Implications and Opportunities for Stakeholders, Webinar, FDA Grand Rounds (cert.) | 10-05-'18 |
| Introduction to ISO 45001, Webinar, Dekra | 17-05-'18 |
| Digital Transformation in Life Sciences: Making the Business Case While Managing the Risk, Webinar, Amplexor | 22-05-'18 |
| TFS & Technology – Our Approach to Study Start-Up, Webinar, TFS | 24-05-'18 |
| Understanding the US FDA De Novo Process for Medical Devices Webinar, Emergo | 24-05-'18 |
| Achieve Quality and Operational Excellence Through Digitalization, Webinar, (Biovia) FDAnews (cert.) | 24-05-'18 |
| Update on the new European MDR, Webcast, TUV Sud (RF) | 29-05-'18 |
| Statistical Indices 101: What they are and how to communicate them, Web seminar, Quality digest | 05-06-'18 |
| Clinical Applications of Mesenchymal Stem Cell Derived | |
| Realizing the ROI of Ride Sharing in Clinical Research, Webinar, Clinical Conductor | 21-06-'18 |
| Medical Device's Secret Weapon: R&D Driven Simulation, Webinar, Siemens | 22-06-'18 |
| Outsourcing to CROs: Grand Experiment or Logical Success?, Webinar, goBalto | 26-06-'18 |
| The Effective Design and Development of Preclinical Studies, Webcast, Namsa | 28-06-'18 |
| Eudamed Requirements under the EU MDR and IVDR, Webinar, Emergo | 11-07-'18 |

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| 5 Ways Biopharma and Medical Device Manufacturers Can Accelerate Patient-Centric Innovation, Webinar, Dassault systems (X-Talks) | 11-07-'18 |
| Efficiencies When Delivering a Quality Database: Tools & Techniques for a Successful Clinical Trial. Webinar, Phastar Medrio. | 24-07-'18 |
| ISO 27001, Webinar, Dekra | 28-08-'18 |
| Ready for eSource, Webinar, Cl Conductor | 29-08-'18 |
| Overview of the MDSAP Certification Process Webinar, Emergo | 31-08-'18 |
| 3 Ways to Become a Data-Driven Quality Team Webinar, FDAnews | 12-09-'18 |
| Peer reviewing, Webinar, Publons | 13-09-'18 |
| Past, present and future of Esource, Webinar, X-Talks | 19-09-'18 |
| Data Governance, a Key Prerequisite for Realizing the Value of Next-Generation Regulatory Information Management (RIM) Systems, Webinar, Amplexor (FDAnews) | 18-10-'18 |
| EU MDR: General Safety & Performance Requirements for the Biocompatibility of Medical Devices, Webcast, Namsa | 23-10-'18 |
| Negotiation is Another Word for Problem Solving Confirmation, Webcast, RAPs (EKG Healthcare: cert.) | 23-10-'18 |
| Conducting a Medical Device PMCF Study, Webinar, Emergo | 30-10-'18 |
| Elevating Research Impact: Pragmatic Clinical Trials and the IRB, Webinar, Quorum | 06-11-'18 |
| Designing Clinical Trials for Success without Breaking the Bank, Webcast, RAPs (cert.) | 07-11-'18 |
| EU MDR Strategies: How to Achieve a Market Advantage While Streamlining Regulatory Compliance, Webinar, X-Talks | 09-11-'18 |
| Gain Recognition for Research by Speaking the Language of Healthcare Executives, Webinar, Bio-optronics (Clin Cond; cert) | 29-11-'18 |
| How MDR impacts Clinical Data and Mobile and Digital Health Applications, Webinar, Amplexor (FDAnews) | 06-12-'18 |
| How MDR Impacts Translation Requirements, Webinar, Amplexor (FDAnews) | 13-12-'18 |
| eConsent - The Good, the Bad, and the Regulatory Webinar, (Clin Cond; cert) | 27-02-'19 |
| What You Need to Know About FDA Regulation of Medical Product Promotional Labeling Confirmation, Webcast, RAPs (cert.) | 06-03-'19 |
| The General Data Protection Regulation (GDPR) and its Impact on Human Factors Studies, Webinar, Emergo | 14-03-'19 |
| EU MDR - Requirements & Implementation - A Virtual Event, Webinar, Med Tech Int. | 17-07-'19 |
| Standing Out in the Site Selection Process: 5 Must-Knows for Research Sites, Webinar, Bio-optronics (Clin Cond; cert) | 31-07-'19 |

**Meeting**

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| MEDTEC meeting, Stuttgart, Duitsland. | 12-04-'16 |
| MEDTEC meeting, Stuttgart, Duitsland. | 05-04-'17 |
| Compamed Medica, Dusseldorf, Duitsland | 12-11-'18 |