Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Clinical Evaluation Report for Europe and MEDDEV Expectations: Impact with New Medical Device Regulations (MDR)

Zurich, Switzerland

November 29th & 30th, 2018

9:00 AM to 5:00 PM

Price

Price: **$1,895.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$5,685.00** You Save: $3,790.0 (40%)*

~~$9,475.00~~

Register for 10 attendees

Price: **$10,422.00** You Save: $8,528.0 (45%)*

~~$18,950.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

David R. Dills

Global Regulatory Affairs & Compliance Consultant and President, NovaQual

David R. Dills, Global Regulatory Affairs & Compliance Consultant, Interim President, currently provides global regulatory affairs, compliance and quality consultative services for early-stage and established Class I/II/III medical device, including combination products, In Vitro Diagnostics, nutraceuticals/supplements, cosmetics and biopharmaceutical manufacturers in multiple medical specialties and therapeutic areas on the global landscape, and has an accomplished record with more than 26 years of experience in the areas of Regulatory Affairs, Compliance and Quality Systems. He has been previously employed, with increasing responsibilities, by medical device manufacturers and consultancies, including a globally recognized CRO, and has worked directly with manufacturers engaged in compliance remediation activities and services involving consent decrees, CIA's, warning letters,483 observations, and customer generated compliance events.

Why you should attend

- Introduction to MEDDEV 2.7.1, Revision 4 (2016)
- This revised MEDDEV is generated within a context of increased scrutiny on the Notified Bodies (NB) by the Joint Assessments from the Competent Authorities, which has led to an increase in the level of review the NB exercise over clinical evaluations
- Frequency for updating the CER is also much more prescriptive now and you must define and justify the frequency, based on "significant risk" of the device, as well as how "well-established"
- One of the largest changes in this revision, the demonstration of "equivalence" is much harder now
- Revision will lead to more clinical investigations, probably of larger size and notified bodies will be looking more closely at how all the essential requirements are met, including those regarding usability
- Manufacturers should start discussing with their notified bodies how they will start implementing these new requirements and to start performing their gap assessments and resource needs-assessments now
- General considerations on updating the clinical evaluation

Agenda:

Day One

Lecture 1: Clinical Evaluation Report and MEDDEV

- Define Scope and Plan the Clinical Evaluation
- Clarification: Frequency of updates to the Clinical Evaluation Report (CER)
- Identification of Pertinent Data
- Appraisal of Pertinent Data
- Analysis of Clinical Data, Draw Conclusions
- Finalize the CER: What should it look like?
- New requirement: Qualifications of report authors and evaluators
- Specific and measurable objectives for the CER
- Establishing the state of the art
- Scientific validity of data
- Equivalence
- Access to data for equivalent devices
- When is a clinical investigation required?
- Risk-benefit
- Post Market Surveillance (PMS) and Post Market Clinical Follow-up (PMCF)
- Table of Contents for a CER (example)
- Given the guarantee that all clinical support documentation is going to need to be re-evaluated and revised to meet the new legislative criteria under the new MDR, coupled with the realization that Notified Bodies are going to be inundated, we need to embark on clinical compliance now

Who will benefit:

Personnel who want to know all aspects of the CER process and MEDDEV and the impact from the new MDR for EU. Medical device professionals in areas of quality and regulatory affairs, design, risk management, postmarket activities, R&D, and manufacturing, who work for manufacturers that market devices in the EU. Employees and personnel who will benefit include:

- All levels of management and departmental representatives any anyone who desire a better understanding or a "refresh" overview of MEDDEV 2.7.1, Revision 4
- Senior Management
- Regulatory Affairs Managers and RA SME's
- Quality Managers
- Design, Development, Manufacturing and Marketing Managers

Day Two

Lecture 2: Clinical Evaluation Report and MEDDEV

- CER Assessment
- Clinical Evaluation Plan and Strategy
- Clinical Literature Review Safety and Performance and Examples
- Preparing, writing and filing a new CER
- Conducting a comprehensive literature review and formal assessment
- Conduct a Literature Review in a few easy steps
- Performing yearly gap analyses of MEDDEV regulations versus the existing CER
- Creating timelines for updating existing CERs, training staff
- Updating existing CERs
- Ensuring compliance with new requirements
- Any upfront or follow-on processes that may help drive commercialization
- Clinical Evidence"? Put simply:
- Clinical Data + Expert Review = Clinical Evidence
- References and Guidance
- Industry Trends

Lecture 3: Consulting Case Study Practice

- Participants role play consulting with instructor on CER examples
- Avoid frequent pitfalls of clinical regulatory submissions
- Provide robust documentation in support of the clinical safety and performance of your device
- Ensure continuing compliance throughout device lifecycle

Lecture 4: Case Study Practice

- Practice on a project relevant to participants' organization
- Best Practices and Trends - A good clinical evaluation is not just a European thing. It can be enormously helpful in a 510(k) in addressing equivalence with predicate device(s). After all - that's what a literature review is partly doing - looking at (all the) other devices in the market and their performance as it is relevant to your device.

Lecture 5: Interactive Exercises and Discussions

- Case studies
- Examples
- FAQ's
- Q&A

Questions and Summary

Recap of Day 2

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
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Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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