Le RDV du DIV®

3rd edition

30th & 31st MAY 2023

"The unmissable rendez-vous for all **IVD** stakeholders"

MAIN TOPICS

Post-market surveillance

Compliance process for the design and development of IVDs

IVDDs and sustainable development issues

thecamp
Aix-en-Provence

Training
2 training days in a convivial setting.

Networking
A friendly evening to facilitate exchanges between participants.

Round table
Feedback from three NBs and manufacturers.

L'institut

DAY 1

TUESDAY 30 MAY

01 **OPENING COFFEE**
1:30PM TO 2:00PM

02 **WELCOME**
2:00PM TO 2:10PM - FLORENT GUYON (NEXIALIST)

03 **IVDR: CURRENT STATE AND PERSPECTIVES**
2:10PM TO 2:40PM - FRÉDÉRIC FORTIS (SIDIV)

One year after the date of application, what is the current state and what are the perspectives.

04 **APPLYING RISK MANAGEMENT MONITORING TO POST MARKET SURVEILLANCE & POST MARKET PERFORMANCE FOLLOW-UP: MAKING SENSE OF THE SURVEILLANCE STRATEGY**
2:40PM TO 3:20PM - NATALIE MCROBERTS (MAGNETOSPHERE LTD)

In this presentation we look at the interaction between risk management monitoring (per ISO 14971:2019) and post market surveillance (per the IVDR). We discuss about strategies for monitoring and surveillance, including the types of surveillance processes, and how to decide on data sources, how to use this data for maximum benefit and the limitations of this data.

05 **HOW TO OPTIMIZE THE PMS PROGRAM WHEN YOU HAVE A PRODUCT PORTFOLIO WITH A LARGE NUMBER OF REFERENCES**
3:20PM TO 4:00PM - SUE SPENCER (QSERVE)

The big PMS question for all manufacturers is "how much is enough?"

When you have a large portfolio of devices this becomes even more important. This session will discuss strategies to successfully achieve the appropriate balance whilst meeting regulatory expectation. It will also look at the flow of information post market, the challenges of acquiring those informations as well as analyzing them.

06 **BREAK & DISCUSSIONS**
4:00PM TO 4:25PM

07 **ENSURING COMPLIANCE IN IVD POST-MARKET SURVEILLANCE: BEST PRACTICES FOR DEVELOPING PMSR/PSUR**
4:25PM TO 5:05PM - CARLOS GALAMBA (MDX CRO)

This session will delve into the intricacies of Post-Market Surveillance Reports (PMSRs) and Periodic Safety Update Reports (PSURs), including the expectations of Notified Bodies in these areas. Attendees will gain a deeper understanding of the unique challenges associated with the classification and novelty of In-Vitro Diagnostics (IVDs) and how these factors impact PMSR and PSUR expectations. We will also provide an in-depth examination of the PSUR guidance for medical devices, with a specific focus on its applicability to IVDs and the key considerations when utilizing this guidance in the context of diagnostics. Additionally, attendees will learn about the integration of PMS outputs into the performance evaluation process and how to effectively use this data to improve the safety and performance of their IVD medical devices.

08 **ROUND TABLE: NB EXPECTATIONS IN TERMS OF PMS**
5:05PM TO 6:00PM - MARTA CARNIELLI (TÜV SÜD), CATHERINE HOLZMANN (GMED) AND ALEX LAAN (BSI)

NB expectations in terms of PMS at the time of application, during technical documentation conformity assessment and/or during organization compliance assessment.

09 **BREAK & DISCUSSIONS**
6:00PM TO 6:30PM

10 **NETWORKING EVENT**
6:30PM TO 10:00PM - JULIEN NIZRI (AFNOR CERTIFICATION) AND PHILIPPE SISSOKO (EUROFINS)

Cybersecurity: framework and challenges for IVD manufacturers
Buffet

DAY 2

WEDNESDAY 31 MAY

01 **OPENING COFFEE**
8:30AM TO 9:00AM

02 **HOW THE INTENDED PURPOSE IS BASED/ ROOT OF THE COMPLIANCE PROCESS**
9:00AM TO 9:45AM - JULIEN SENAC (TÜV SÜD)

03 **HOW DEMONSTRATING COMPLIANCE WITH EGSPS UNTIL ALL THE NECESSARY STANDARDS ARE HARMONIZED?**
9:45AM TO 10:25AM - CORINNE DELORME (NEXIALIST)

Following harmonized standards confers presumption of conformity to GSPRs . How to do when they do not exist?

04 **BREAK & DISCUSSIONS**
10:25AM TO 10:50

05 **USABILITY ENGINEERING AND IVDR – REGULATORY REQUIREMENTS AND HOW-TO'S**
10:50AM TO 11:30AM - MICHAELA KAUER FRANZ (CUSTOM INTERACTIONS GMBH) & SANDRA NEIDHÖFER (METECON)

Since the new IVDR usability engineering is more in the focus of notified bodies than ever before. But: What does the IVDR actually require in terms of usability engineering and how does the IEC 62366-1 relate to that ? Within this talk, we will give an overview on regulatory requirements for usability engineering for IVDs and present you with do's and don'ts for the practical usability engineering.

06 **IVDS AND SUSTAINABLE DEVELOPMENT**
11:30AM TO 12:15AM - STEVE LEE (ABHI)

Overview of sustainability; some stats on healthcare sustainability, the effects of climate change on health.

The different ways that sustainability is being approached in healthcare; increased remote care such as remote triage and monitoring, decreasing emissions through electric cars and renewable energy resources, reducing waste, recycling medical devices, implementing circular economy.

Use of IVD's for changing the patient pathway; if patients get diagnosed sooner, they have less resource intensive hospital visits, better for both patient and planet.

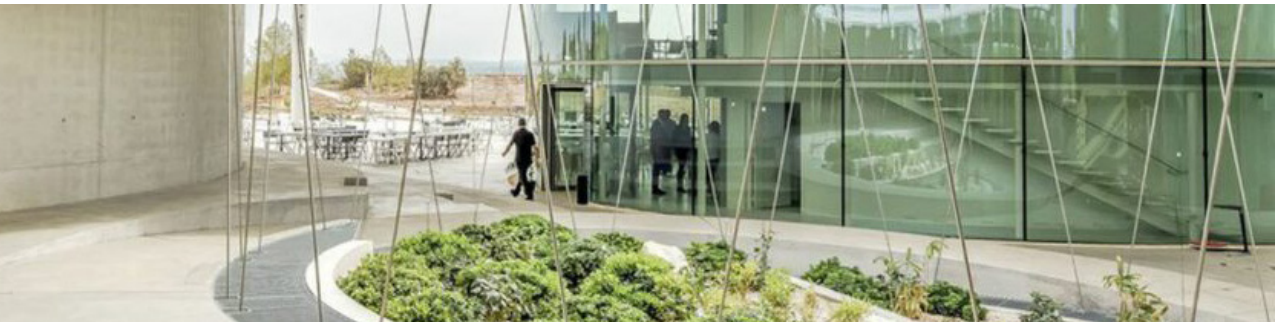
Some examples of where this has been achieved and how this has benefited patients/ the manufacturer.

07 **LUNCH**
12:15AM TO 2:00PM

08 **DECARBONIZING THE HEALTHCARE SECTOR - LESSONS LEARNED FROM PHARMA AND PRIVATE/PUBLIC PARTNERSHIPS**
2:00PM TO 2:40PM - FREDERIK VAN DEURS (GREEN INNOVATION GROUP)

How integrating sustainable development goals in diagnostic in vitro medical devices.

09 **ROUND TABLE: INTEGRATION OF THE SUSTAINABLE DEVELOPMENT IMPERATIVE IN THE DESIGN PROCESS**
2:40PM TO 4:00PM - ARNAUD COLLIN (SEBIA) AND 2 OTHERS MANUFACTURERS (TBD)



An annual training conference on IVD regulation within the XR4.0 program, with the aim to bring together people who have to apply the regulations (manufacturers) and people who assess the compliance of their products and organization (notified bodies, competent authorities).

XR4.0 PROGRAM

Setting up exchanging and sharing opportunities, to create positive synergies between all stakehoders and support changes in the regulatory jobs.

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