

June 28th & 29th



LE RDV DU DIV[®]

2nd edition

Two days of training which bring together the players of the sector (manufacturers, NB, HAS, CA...) in a convivial and favourable framework of exchanges.

"The must-attend event for
DIV contributors"

by  nexialist



Theme

FOCUS : Performance
evaluation



Networking

A convivial evening to
encourage exchanges
between participants



Round table

Feedback from 3 notified
bodies and 3 IVD
manufacturers

CONTACT US

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Thecamp
550 rue Denis Papin,
13100 Aix-En-Provence

Program

FOCUS: PERFORMANCE
PERFORMANCE

TUESDAY, JUNE THE 28TH

Opening & Coffee

Welcome
www.nexialist.fr

One month after the date of application,
what is the situation?
SIDIV

EUDAMED, the latest and experiences so far

Richard Houlihan (EirMed Ltd)

Break & discussions

Legacy product : take advantage of
transitional provisions!
Corinne Delorme (nexialist)

State of the Art : Importance & impact
on technical documentation

Networking event

Round table : how to support medical device companies in their
market access efforts
Buffet



13h30 - 14h

14h - 14h10

14h10 - 15h15

15h15 - 16h

16h - 16h30

16h30 - 17h15

17h15 - 18h

18h - 22h

Program

FOCUS: PERFORMANCE
PERFORMANCE

WEDNESDAY, JUNE THE 29TH

Welcome & Coffee

Do manufacturers really understand the intent
of a performance evaluation?
Robyn Meurant (ACT-IVD)

Establishing a clinical correlation:
Scientific Validity in IVDR
Stephen Lee (ABHI)

Break & Discussions

Uncovering Post-Market Performance
Follow-Up : challenges, lessons learned
and opportunities
Carlos Galamba (RQM+)

Feedback from manufacturers

Impact of IVDR performance evaluation requirements
Sophie LA (Theradiag), Sophie Réhaut (Stago) & others

Lunch and Discussions

Feedback from notified bodies

Lessons learnt about performance evaluation
conformity assessment. Julien Sénac (TÜV Sud), Erica
Conway (BSI) & Jeannette Fareh (GMED)



8h30 - 9h

9h - 9h40

9h40 - 10h20

10h20 - 10h45

10h45 - 11h25

11h25 - 12h30

12h30 - 14h

14h - 16h

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