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FRANKFURT, GERMANY
FEBRUARY 25-26, 2013

3rd Annual

IVD PERFORMANCE EVALUATION AND REGULATORY CONFERENCE

Furthering In-Vitro Diagnostic Innovation and Approval throughout European Member States through Greater Understanding of the Risk-Based Classification System and Performance Evaluation Guidelines under the Proposed IVD Draft Regulation

PROGRAM OVERVIEW:

The highly anticipated drafted regulatory proposal for European Diagnostic manufacturers was released in September of 2012. The revision of the IVDD has been an on-going process for some time now and manufacturers are looking forward to a new, harmonized set of rules that aim to simplify the commercialization process and improve product safety and efficacy through increased performance evaluation requirements. In the 3rd Annual IVD Regulatory & Performance Evaluations Conference, speakers and attendees will experience an unprecedented opportunity for discussion and debate that is focused most specifically on the diagnostic market – a truly one of a kind program that highlights the challenges so specific to this industry.

Many industry regulators and clinicians are gearing up to transition and prepare as best they can as the draft regulations are being presented to the Parliament and the Counsel. This meeting will discuss and address optimal methods for product classification under the new risk-based system, as well as focus on the transition period and timeline in which manufacturers must implement the new regulations.

One area of particular focus for the 2013 meeting will be companion diagnostics, which have been hailed as a revolutionary tool in the future of medicine. However, most EU diagnostic manufacturers must overcome a variety of obstacles if they are to achieve developmental and commercial success in a complex medical landscape. Presentations and discussions with prominent companion diagnostic manufacturers and competent authorities will provide insight and guidance for success in companion diagnostics performance evaluations and regulatory approval.

Like all Q1 programs, the focus will not only include educational sessions, but also formal and informal networking opportunities through various coffee and luncheon breaks, as well as sessions aimed at group discussion. Through highlighting the specific regulatory and performance evaluation challenges of the diagnostic market in Europe, this conference will certainly be a must-attend for the 2013 event calendar.

CONFERENCE SPONSOR:

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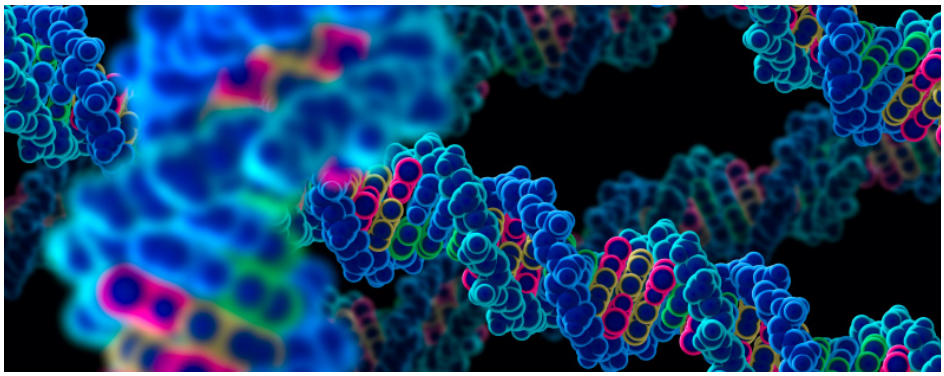

DISTINGUISHED PRESENTERS INCLUDE:

Dr. Petra Kaars-Wiele
Director International Regulatory Affairs & Division Labeling
ABBOTT GMBH & CO KG

Prof Martina Cornel
Member of EASAC-FEAM Working Group Direct-to-Consumer Genetic Testing
CLINICAL GENETICS & EMGO INSTITUTE FOR HEALTH & CARE RESEARCH

Geert Callaerts
Director, Regulatory Affairs
JANSSEN DIAGNOSTICS

Nick Baker
Technical Manager, IVD
NOTIFIED BODY LLOYD'S REGISTER QUALITY ASSURANCE (LRQA)

Laurent Oliviero
Supervisor, Safety Risk Management & Surveillance
ORTHO CLINICAL DIAGNOSTICS

Sabine Ohse
Head of Medical Device Certification
BSI

Dr. Maurizio Suppo
Principal Consultant
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Koen Barto
IVD Project Manager
DEKRA CERTIFICATION BV

Sam Martin
Senior Regulatory & Clinical Affairs Manager
QIAGEN

Dr. Hubert Bayer
Director of Global Regulatory Affairs
ROCHE DIAGNOSTICS

Dr. Christian Fulda
Partner
JONES DAY

Dr Jens Pfannkuche
Head of Business Development
THERMO FISHER SCIENTIFIC

Julia Shannon
Manager
QIAGEN

Dirk Stynen
President and Principal Consultant
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Geraldine Lissalde Bonnet
Public Policy Manager Healthcare
GS1

Dr. Dieter Schoenwald
Manager In-Vitro Diagnostics
TÜV SÜD PRODUCT SERVICE GMBH

Marlène Chavaroche
IVD Certification Project Manager
LNE/G-MED

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Journal of Medical Device Regulation

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DAY ONE / MONDAY, FEBRUARY 25

THIRD ANNUAL IVD PERFORMANCE EVALUATION AND REGULATORY CONFERENCE

9:00 CONFERENCE REGISTRATION & WELCOME COFFEE

9:25 CHAIRPERSON'S OPENING REMARKS

Dr. Ivor Barrett, *Sr. Staff Engineer/IVDD Certification Manager/Lead Auditor*
UL INTERNATIONAL (UK) LTD

9:30 A STATUS UPDATE AND COMPREHENSIVE OVERVIEW ON EU IVD REGULATIONS

The European Commission will soon shift from the current regulatory directive for in-vitro diagnostic to stricter regulations that all member states are required to follow, leaving no room for individual interpretation. Amid growing public expectations and the advancement of technological innovation, the Commission decided to review and revise the legal framework to improve and strengthen a system which had previously been criticized for being difficult and lacking flexibility. While these regulations won't be final for at least another year, the IVD industry anxiously awaits any clarity or guidance as their responsibility guidelines will be immediate.

- Insight into proposed regulation timeline and key deadlines
- Understanding the implications of the revised privacy framework
- Compare and contrast revised IVD with MDD

Sabine Ohse, *Head of Medical Device Certification*
BSI

10:15 OUTLINING AND UNDERSTANDING NOTIFIED BODY EXPECTATIONS UNDER THE PROPOSED IVD REGULATION

The role of the notified body is critical for ensuring the highest level of product safety, and similar to IVD manufacturers, notified bodies will undergo a number of changes now that the IVD regulation has been released. The regulation mandates that notified bodies strengthen their vigilance on manufacturers through methods such as unannounced audits and assessments. While the regulation won't go into effect for another few years, one thing is clear: notified body involvement in IVD conformity assessment will accelerate.

- Notified Body reactions and interpretations to regulation
- Discussing changes and requirements for self-test IVDs
- Forecasting potential impacts on the institution of notified bodies

Nick Baker, *Technical Manager, IVD*
NOTIFIED BODY LLOYD'S REGISTER QUALITY ASSURANCE (LRQA)

11:00 EXAMINING THE INTRICACIES OF THE RISK-BASED IVD CLASSIFICATION SYSTEM

The migration from a list-based classification system to a risk-based approach has been one of the most talked about topics regarding the recast of the IVD Directive. The EU Commission has crafted a series of 7 classification rules which will assist regulatory teams when deciphering a test's appropriate risk class and requirements. While somewhat similar to the framework proposed by the former GHTF, this system is more specific and parallel to those of the updated MDD. The adoption of this system is sure to result in both benefits and challenges for the industry as well as regulators.

- Key risk-based outcomes for manufacturers
- Weighing cost/benefit analysis
- Appropriate companion and molecular diagnostic classification
- Special considerations in genetic test classification

Dr. Hubert Bayer, *Director of Global Regulatory Affairs*
ROCHE DIAGNOSTICS

Dr. Dieter Schoenwald, *Manager In-Vitro Diagnostics*
TÜV SÜD PRODUCT SERVICE GMBH

12:10 LUNCHEON FOR ALL CONFERENCE PARTICIPANTS

1:10 NEW REQUIREMENTS FOR POINT-OF-CARE PRODUCTS AND SELF-TEST IN CONFORMITY ASSESSMENT PROCEDURES

Companies that develop self-test products will see the most drastic alterations once the draft IVD Commission proposal has been released. Under the previous classification system, all IVDs were considered for general use and deemed low-risk unless they were produced for self-testing or fell into one of the two lists of high-risk products. Various devices that did not previously require interactions with notified bodies will soon be required to, and because these tests require notified body approval, they will also have more strict requirements than other point of care diagnostics.

- Optimal strategies for obtaining notified body approval on self-tests
- Developing and implementing adequate QMS
- Third party involvement in monitoring QMS

Koen Barto, *IVD Project Manager*
DEKRA CERTIFICATION BV

1:55 CLARIFICATION AND UPDATED REGULATIONS FOR LABORATORY DEVELOPED TESTS

The vast majority of all diagnostic tests developed worldwide are self-certified and considered low risk. The proposal outlines specific requirements for clinical validation manufacturers are responsible for determining whether they've complied with the appropriate requirements and if the product warrants a CE mark. The draft regulations outlines specific instructions for laboratory developed tests and includes explicit requirements with regards to clinical validation.

- Proposed laboratory developed test policies and procedures
- Effective methods for complying with regulations
- Evidence required for intended use

Dirk Stynen, *President and Principal Consultant*
QARAD

2:40 DEFINING REGULATIONS AND PERFORMANCE EVALUATION CRITERIA FOR GENETIC TESTS

While genetic diagnostic development and testing has grown significantly within the past decade, there are few regulatory controls in place. These tests have been a subject of intense policy debate as they are a highly complex and technical issue of public concern. Under the current directive, genetic tests are not subject to independent pre-market review as they are considered low risk. Professional standards and regulations for genetic tests currently differ by location, and there has been a call from the industry for a more globalized, concise legal framework.

- Potential for a harmonized definition of genetic testing
- Strategic solutions for developing genetic tests
- Issues and debate surrounding direct-to-consumer (DTC) genetic tests

Prof Martina Cornel, *Member of EASAC-FEAM Working Group Direct-to-Consumer Genetic Testing*
CLINICAL GENETICS & EMGO INSTITUTE FOR HEALTH & CARE RESEARCH

3:25 COFFEE & NETWORKING BREAK

3:45 PANEL DISCUSSION: RECAST IMPLICATIONS AND PERSPECTIVE FROM VARIOUS IVD STAKEHOLDERS

Regulatory obligations can be quite burdensome for medical device and IVD manufacturers as there is no standard across EU member states. The Commission has recently released the draft regulations for the revision of the IVD and MDD regulations; however, it will still be some time before the final text is revealed and implemented. A globalized legal framework has potential benefits and challenges for all parties, including industry, patients and regulators; understanding each perspective can assist in alleviating some of the potential implementation hurdles.

- IVD regulation interpretations and applicable norms
- Defining the level of adequacy for evidence and data
- Strategies for meeting requirements with appropriate documentation

MODERATOR: Dr. Maurizio Suppo, *Principal Consultant*
QARAD

PANELISTS: Dr. Petra Kaars-Wiele, *Director International Regulatory Affairs & Division Labeling*
ABBOTT GMBH & CO KG

Koen Barto, *IVD Project Manager*
DEKRA CERTIFICATION BV

Marlène Chavaroche, *IVD Certification Project Manager*
LNE/G-MED

4:45 CURRENT AND FUTURE E-LABELING POLICIES AND PROCEDURES FOR EUROPEAN DIAGNOSTICS

Electronic instructions and labeling for European devices is another area said to be included in the upcoming draft IVD regulation. Under the current directive, requirements with regards to e-labeling is nonexistent as the directive was developed at a time when e-labeling wasn't common practice. E-labeling has the potential to reduce the risk of misinterpretation, as the instructions are more readily available in various languages throughout the EU. Current proposal does contain explicit requirements

- Defining essential elements for risk assessment
- Eucomed initiatives for increased e-labeling regulations
- E-labeling provisions in draft Commission proposal

Dr. Petra Kaars-Wiele, *Director International Regulatory Affairs & Division Labeling*
ABBOTT GMBH & CO KG

5:30 DAY ONE CONFERENCE CONCLUSION

DAY TWO / TUESDAY, FEBRUARY 26

THIRD ANNUAL IVD PERFORMANCE EVALUATION AND REGULATORY CONFERENCE

9:00 CONFERENCE REGISTRATION & WELCOME COFFEE

9:05 CHAIRPERSON'S OPENING REMARKS

Dr. Maurizio Suppo, *Principal Consultant*
QARAD

9:10 INCREASED EVIDENCE REQUIREMENTS FOR DIAGNOSTIC PERFORMANCE EVALUATIONS

In the release of the upcoming draft regulation, the EU Commissions will propose modifications and additions to performance evaluations; specifically that clinical evidence should be required for all risk classes excluding the lowest. These amplified requirements have the potential to lengthen and complicate the approval process for many manufacturers who were previously permitted to conduct independent studies. A recent industry survey found an overwhelming majority of respondents believed the current clinical evidentiary requirements to support IVDs need to be clarified, emphasizing that the system is misleading and often misinterpreted.

- Strategies and cost-effective methods for complying with regulations
- Details on clinical evidence and utility
- Demonstrating validity through clinical evidence

Dr. Jens Pfannkuche, *Head of Business Development*
THERMO FISHER SCIENTIFIC

9:55 PRACTICAL GUIDANCE FOR CONDUCTING IVD PERFORMANCE EVALUATIONS

Determining an appropriate diagnostic study protocol, particularly defining the intended patient population for the test, can be especially difficult for clinical development teams. Requirements for the execution of performance evaluations or clinical trials in the EU are provided outlined in the Clinical Trial Directive, which specifies principles and detailed guidelines for good clinical practice (GCP), as well as requirements for manufacturing or importation of such products. While diagnostic studies are governed by similar regulatory requirements as other devices, diagnostic agents are used to diagnose and monitor diseases/conditions and are not for treatment; performance evaluations must be adapted for these purposes.

- Considerations for appropriate study strategy and design
- Ethical considerations and risk management
- Benchmarks for measuring diagnostic consistency

10:40 COFFEE & NETWORKING BREAK

11:00 TECHNICAL REQUIREMENTS AND METHODOLOGIES FOR EFFECTIVE COMPANION DIAGNOSTICS COMMERCIALIZATION

Standards for companion diagnostics have been a top concern of many competent authorities and industry manufacturers throughout Europe for some time. Strict regulation of these products is necessary, but still developing in the EU, and most manufacturers who develop these products currently do so through self-certification. While current regulations vary by country, harmonized requirements regarding companion diagnostics are said to be included in the release of the upcoming IVD regulation draft.

- Analyzing potential draft regulations
- Interpretations and primary takeaways on FDA companion diagnostic regulations
- Appropriate labeling for companion diagnostics

Dr. Christian Fulda, *Partner*
JONES DAY

11:45 KEY SUCCESS FACTORS FOR CONDUCTING COMPANION DIAGNOSTICS PERFORMANCE EVALUATIONS IN EU MEMBER STATES

Companion diagnostics are forecasted to have significant growth within the next few years and countless manufacturers are anxious to begin developing performance evaluations. One of the largest Swiss-based pharmaceutical manufacturers recently announced that 60% of their pipeline will come paired with diagnostics, exemplifying their investment in personalized medicine. In order to successfully develop a companion diagnostic test, clinical teams must address a number of key factors that promotes consistency and widespread use of their products.

- Optimal strategy design for performance evaluations
- Ensuring compliance in companion diagnostic studies
- Partnering & strengthening relationships with pharma for co-development

Sam Martin, *Senior Regulatory and Clinical Affairs Manager*
QIAGEN

Julia Shannon, *Manager*
QIAGEN

12:30 LUNCHEON FOR ALL CONFERENCE PARTICIPANTS

1:30 GUIDANCE FOR QUALIFYING AND CLASSIFYING STAND-ALONE SOFTWARE

Under current EU directives, software that supports or accompanies a diagnostic or device in its function is also regulated as a diagnostic or device. The EU Commission published guidelines earlier this year to provide clarity and further definitions regarding the classification of stand-alone software, including mobile apps, used in healthcare applications. This framework will help regulatory and clinical teams determine if software qualifies as an accessory, an actual part of the device, a standalone medical software or general software.

- Reviewing past, present and future stand-alone policies
- Defining and analyzing qualifying criteria
- Understanding and utilizing decision trees

Geert Callaerts, *Director, Regulatory Affairs*
JANSSEN DIAGNOSTICS, A JOHNSON AND JOHNSON COMPANY

2:15 NEW REQUIREMENTS FOR MEDICAL VIGILANCE & POST MARKET SURVEILLANCE

As innovation continues to expand throughout the IVD industry, both post-market surveillance and vigilance have become absolutely critical to ensuring patient safety. The EU Commission has developed specific post-market regulations in the newly released regulation by introducing an interconnected web portal where manufacturers must report serious incidents and corrective actions, some of which will be publicly available. This will ultimately connect member states and emphasize the importance of collaboration and knowledge share.

- Strategic development for post-market surveillance plans
- Outlining obligations for manufacturers
- Incident reporting requirements for industry

Laurent Oliviero, *Supervisor, Safety Risk Management*
ORTHO CLINICAL DIAGNOSTICS

3:00 ENHANCING IVD TRACEABILITY THROUGH UNIQUE DEVICE IDENTIFICATION (UDI)

Device and diagnostic safety has come under scrutiny as of late with major cases making news and the EU Commission recognizing and stressing the need for greater transparency with patients. Combating these challenges head on, the draft regulation has included specific requirements for all IVDs to be outfitted with unique device indicators (UDI). Other countries have implemented UDI systems enabling the identification of different types of devices and access to useful and relevant data, increasing the effectiveness of post-market safety.

- The impact of UDI on patient safety and supply chain efficiency
- Data standards to fulfill UDI requirements
- Regulatory developments on UDI in Europe and beyond – getting ready
- UDI and traceability – implementation examples

Geraldine Lissalde Bonnet, *Public Policy Manager Healthcare*
GS1

3:45 CLOSING REMARKS

4:00 CONFERENCE CONCLUSION

KEY SPEAKER HIGHLIGHT:

DR. PETRA KAARS-WIELE
Director International Regulatory Affairs & Division Labeling
Abbott GmbH & Co KG

Abbott
A Promise for Life

Diploma and Ph.D. in Organic Chemistry, more than 29 years experience in Regulatory Affairs and Quality Systems for Medical Device, currently responsible for all international regulatory matters, medical event reporting, managing translation for 25 languages and labeling activities at Abbott Diagnostics Division. Petra is located in Germany.
Other activities:
• Chairwoman of the EDMA Globalization Working Party
• Member of the EDMA Regulatory Committee and Technical Forum
• Member of the GHTF SG1, IVD Subgroup representing EDMA, from 2003 until 2012
• Member of the International Task Force and the Blood Safety Working Party of EUCOMED
• Member of European Advisory Board of RAPS, member of the Association of Virology and the German Association of Blood Transfusion

WHO SHOULD ATTEND:

Executives that will find this program of greatest applicability are those working within diagnostic corporations to commercialize new diagnostic tests through CE Marking and the execution of performance evaluations to support CE Mark. Those that require a full understanding of the implications of new directives will also find this event a must attend. Job titles that will be of greatest relevance include Vice Presidents, Directors and Managers falling under the following job functions:

- **Regulatory Affairs**
- **Clinical Affairs**
- **Clinical Science**
- **Clinical Research**
- **Quality Assurance**
- **Bioethics Compliance**
- **Registration Manager**

SPONSORSHIP OPPORTUNITIES:

At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:

- **Experts in Performance Evaluations**
- **Clinical Research Organizations**
- **Regulatory Submission Experts**
- **Risk Management for IVD**
- **Packaging & Labeling Services**
- **Translation Services**
- **Research / Specimen Procurement Services**
- **Biobanks**

PREVIOUS ATTENDEES INCLUDE:

Sr Dir, Strategic Health Initiatives, **Abbott Diagnostics**
Manager, Regulatory Affairs, **Aerocrine AB**
Dir, Reg Affairs & Quality Assurance, **Aerocrine Inc**
Quality Manager, **Alifax**
CEO & President , **AmpTec Gmbh**
Scientific & Technical Coordinator, **Analis SA/NV**
Dir Regulatory Affairs & Quality Assurance, **Atonomics A/S**
Chief Operating Officer, **Atonomics A/S**
Associate Director Health Economics, **Atrium Europe BV**
Regulatory Affairs Manager, **Axis-Shield PoC A/S**
Lawyer, **Axon Lawyers**
Director Medical-Clinical- Scientific Affairs, **Bayer AG**
CRA Manager- Med Affairs & Clinical Ops, **BD Biosciences**
Regulatory Compliance Manager, **BD Biosciences Europe**
Director Regulatory Affairs & Quality Assurance, **Biokit**
Quality Affairs Manager, **Boule Medical AB**
Regulatory Affairs Director, **Boule Medical AB**
Head of Regulatory & Clinical Affairs Healthcare, **BSI Group**
Regulatory Affairs, **Buhlmann Laboratories AG**
Head QA& Reg Affairs, **Buhlmann Laboratories AG**
Quality Assurance Manager, **CellaVision AB**
Quality Assurance Specialist, **CellaVision AB**
Quality Assurance & Regulatory Affairs, **Copan Italia SpA**
Manager Regulatory Affairs, **Copan Italia SpA**
Quality & Regulatory Affairs Manager, **Curetis AG**
Regulatory Affairs Senior Specialist, **Dako**
Regulatory Affairs Specialist, **Dako A/S**
IVD Project Manager, **Dekra Certification BV**
Driector Marketing, **Diagenic ASA**
Regulatory Survey Engineer, **Diagnostica Stago**
Regulatory Affairs Specialist, **DiaSorin SpA**
Quality Mngr Reg. Affairs, **DiaSys Diagnostics Systems**
Technical Assistant, **DiaSys Diagostic Systems GmbH**
Quality and Regulatory Manager, **DNA ELECTRONICS**
Quality Management, **EUROIMMUN Medizinische AG**
Manager Regulatory Affairs, **Exonhit SA**
Regulatory Affairs Manager CE Marking/ EMEA, **Fenwal**
SVP Regulatory Affairs & Quality, **Gen-Probe, Inc**
Associate Dir Regulatory Affairs, **Genzyme Europe BV**
Regulatory Affairs Specialist, **HemoCue AB**
Regulatory Affairs Support, **Horiba Medical**
Mngr, Quality & Reg Affairs, Europe, **Hycor Biomedica ltd**
Quality Assurance, Regulatory Manager, **IDL Biotech AB**
Project Manager, **IHD Innovtive Health Diagnostics**
Senior Manager, Quality, **Illumina**
Dir Intl Regulatory Affairs and Compliance, **Immucor**
Project Manager Diagnostic Dev., **InDex Pharmaceuticals**
Chief Scientific Officer, **InDex Pharmaceuticals**
Development Service Unit Manager, **Innogenetics**
Senior Clinical Developer, **Innogenetics**
Senior Regulatory Affairs Officer, **Innogenetics**
Quality Assurance & Regulatory Specialist, **Inpeco SpA**
Partner, **JONES DAY**
QA and Regulatory Affairs, **Kreatech Diagnostics**
Senior Regulatory Analyst, EMEA, **Life Technologies BV**
AND MANY MORE!