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.

Distinguished Presenters Include:

Michael Fritz  
Manager Regulatory Affairs EMEA & India  
ABBOTT DIAGNOSTICS

Prof Martina Cornel  
Member of EASAC-PEAM 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 Olivier  
Supervisor, Safety Risk Management & Surveillance  
ORTHO CLINICAL DIAGNOSTICS

Sabine Ohse  
Head of Medical Device Certification  
BSI

Dr. Maurizio Suppo  
Principal Consultant  
QARAD

Koen Barto  
IVD Project Manager  
DEKRA CERTIFICATION BV

Neil McLachlan  
Senior Manager, Regulatory Affairs  
QIAGEN

Dr. Hubert Bayer  
Director of Global Regulatory Affairs  
ROCHE DIAGNOSTICS

Gail Radcliffe  
Affiliate Principal Regulatory Consultant  
APTIV SOLUTIONS

Dr Jens Pfannkuche  
Head of Business Development  
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Julia Shannon  
Manager  
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President and Principal Consultant  
QARAD

Geraldine Lissalde Bonnet  
Public Policy Manager Healthcare  
GS1

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

Catherine Holzmann  
IVD Department Manager  
LNE/G-MED CERTIFICATION DIVISION

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FRANKFURT, GERMANY  
FEBRUARY 25-26, 2013  
Sheraton Frankfurt Congress Hotel
DEKRA CERTIFICATION BV

10:30 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
TUV SUD 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
APTIV SOLUTIONS

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

In-vitro diagnostic tests are getting more complicated and regulatory bodies across the world are struggling to ensure placement of safe and effective products in the marketplace. Regulations are based on risk: for IVDs the riskiest products are those on which patient management hinges. Because companion diagnostics determine who will benefit from treatment with a particular drug and who might be harmed, these products are the focus of intense regulatory scrutiny. An updated IVD directive was released in September and a revised companion diagnostic guidance document is expected to be released by the US FDA by Q2, 2013. An overview of regulations will be presented with historical case examples. Taking into consideration the proposed changes, these examples will also be used to demonstrate the pathway to market that companion diagnostics will take in the future.

• Review IVDD update
• Discuss pertinent updates to IMDR (GHTF) IVD clinical evaluation documents
• Interpret current FDA presentations and expected revisions to companion diagnostic guidance

Gal Radcliffe, Affiliate Principal Regulatory Consultant
APTIV SOLUTIONS

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

Neil McLachlan, Senior Manager, Regulatory Affairs
QIAGEN

12:30 LUNCHEON FOR ALL CONFERENCE PARTICIPANTS

TUESDAY, FEBRUARY 26

DAY TWO
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**

**WHO SHOULD ATTEND:**

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, **Biotik**
- 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**
- Director Marketing, **Diagnostic ASA**
- Regulatory Survey Engineer, **Diagnostica Stago**
- Regulatory Affairs Specialist, **DiaSorin SpA**
- Quality Mngr Reg. Affairs, **DiaSys Diagnostics Systems**
- Technical Assistant, **DiaSys Diagnostics 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**
- Mgr, Quality & Reg Affairs, Europe, **Hycor Biomedica ltd**
- Quality Assurance, Regulatory Manager, **IDL Biotech AB**
- Project Manager, **IDH Innovative 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, **Immugenetics**
- Senior Clinical Developer, **Immugenetics**
- Senior Regulatory Affairs Officer, **Immugenetics**
- 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!

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