Throughout Europe, diagnostic corporations are continually developing new and ground-breaking diagnostic tests that are revolutionizing the method in which patients are diagnosed, as well as the way decisions are made regarding the course of treatment. Although the industry is well established throughout the continent, regulators have been slow to provide concrete guidance to these innovative companies on regulatory clearance, as well as on the performance evaluations that ultimately guide companies, users and regulators on the appropriate and intended use for the product. In the 2nd Annual IVD Regulatory & Performance Evaluations Conference, speakers and participants will experience an unrivaled 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.

With the IVD Directives still in flux, several sessions will be dedicated to forthcoming directive updates, and how companies can not only prepare for these changes, but also implement the changes in a straightforward and comprehensive manner. Through perspectives ranging from the European Commission to Notified Bodies and industry experts, the program will provide the well-rounded approach required when addressing such evolving standards. Key areas to watch, along with recast timelines and implementation approaches will be central to these sessions.

Performance evaluations will also be discussed during this program, covering a wide range of topics, from initial study design considerations to sample sizes and practical considerations in sample disposal. Challenges faced in conducting this type of research for diagnostic tests are tremendous and entirely different from the challenges faced by pharmaceutical and device corporations in their clinical research. Focusing on diagnostic performance evaluations and covering the full range of study design through publication and use will provide participants with the critical information required to succeed in this market. 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 challenges of the diagnostic market in Europe, this conference will certainly be a must-attend for the 2012 event calendar.
8:00 REGISTRATION & CONFERENCE WELCOME
8:45 CHAIRPERSON’S OPENING REMARKS

9:00 UPDATES ON THE CURRENT STATE OF THE IVDD RECAST
The EU IVD community is anxiously awaiting the release of the draft guidance on the recast of the IVDD and anticipates its release within the next few months. While the EU commission has held many public meetings and consultations regarding the potential revisions, as well as provided information on what these changes may entail, many manufacturers remain concerned about how these changes will impact not only their organizations, but the IVD industry as a whole.
- Forecasted changes and guidance on potential revisions
- Key takeaways from public consultations
- Analyzing recast impacts on IVD manufacturers of all sizes
- Discussing recast timeline and additional resources

Dr. Gert Bos
Head of Regulatory & Clinical Affairs Healthcare
BSI

9:45 OVERVIEW OF EU LEGISLATION & FORTHCOMING REGULATORY DEVELOPMENTS FOR IVDS
The recast of the In-Vitro Diagnostics Directive (IVDD) is one of the most discussed topics among manufacturers as well as regulators; however, there are a number of other regulatory policies and developments that manufacturers need to stay abreast of such as labeling laws and revisions to related directives. While the GHTF continues to strive for a harmonized set of standards for all member states, it is essential for manufacturers to be aware of multiple policy and guideline developments.
- Languages requirements
- Updates on Eudamed
- Label specifications and regulations

Dana Olsen
Regulatory Affairs Senior Specialist
DAKO

10:30 COFFEE & NETWORKING BREAK

10:50 DEFINING NECESSARY REQUIREMENTS AND CONSIDERATIONS FOR IVD PERFORMANCE EVALUATIONS
The proliferation of IVD Performance Evaluation studies in the EU and abroad continues to increase as new diseases and technologies emerge. While performance evaluations are mentioned in the current IVDD, there is little detail on the practical elements and requirements of IVD studies. While EU member states have attempted to develop a harmonized standard of regulations, a great deal of concern and uncertainty remains for manufacturers looking to conduct studies in other countries.
- Understanding the notification process in EU member states
- Best practices for obtaining study approval
- Defining and understanding elements of study design and practicality
- Professional vs. self-test products

Dr. Sigrid Nick
Head of IVD Unit
PAUL EHRLICH INSTITUTE

11:35 IN-DEPTH ANALYSIS OF PERFORMANCE EVALUATION STUDIES UTILIZING LEFTOVER SPECIMENS
Performance evaluation studies utilizing leftover specimens, or “remnants of specimens collected for routine clinical care or analysis that would otherwise have been discarded”, are common practice in many EU member states and have led to the success of many IVD tests. While these studies offer IVD manufacturers many benefits, they can also be a significant challenge due to differing regulations for leftovers which vary according to location.
- Defining country-specific regulations (focus on Germany, overview of France, Netherlands, UK)
- Access to specimens, including classified leftover specimens
- Strategies for maintaining study integrity and publishing outcomes
- Evaluating the time and cost-effectiveness of leftover specimens

Dr. Stephan Lunau
Manager QM
SYSMEX EUROPE

12:20 LUNCHEON FOR ALL CONFERENCE ATTENDEES, SPEAKERS, & SPONSORS

1:50 TRENDS IN LABELING AND E-LABELING FOR IVDs
Evolutions in regulations and guidance documents create new problems and opportunities. In the first part of the presentation, the impact of new labeling standards and of the CLP regulation will be discussed. The second part of the presentation will focus on e-labeling. The regulatory and practical hurdles for implementing e-labeling solutions will be described and practical solutions will be proposed, including the demonstration of a compliant e-labeling website and outsourcing possibilities.

Dirk Stynen PhD
President and Principal Consultant
QARAD

2:35 GUIDANCE ON NEW EU VIGILANCE PROGRAMS FOR IVDs
There has been a vast increase in IVD post market surveillance and vigilance in the past decade due in part to the passing of the IVDD. This has been a challenge for many manufacturers as they are required to notify each member state’s national authority regardless of where their product is marketed. It is essential for EU IVD manufacturers to invest additional resources across multiple locations to appropriately communicate any corrective safety action and adverse events.
- Defining and implementing IVD vigilance requirements
- Trend Reporting- Current and future presence for IVDs
- Forecasting vigilance under the recast of the IVDD

Dr. Maurizio Suppo
Vice President, Standardization, Technology & Industry Affairs
SIEMENS AG

3:20 COFFEE & NETWORKING BREAK

3:40 OUTLINING BEST PRACTICES FOR IVD REGISTRATION IN EU MEMBER STATES
Despite numerous attempts to develop a harmonized set of IVD registration regulations, EU member states continue to operate under their own individual requirements apart from the IVDD. This is an ongoing struggle for manufacturers as the burden of individual registration requirements continues to expand as more locations emerge for performance evaluation studies. While CE marking of a product does indicate that the product may be legally placed on the market, a number of additional registration hurdles such as language and data requirements must also be addressed.
- Key requirements and timelines for registration
- Understanding the registration process in EU member states
- Resources for further guidance

4:25 REGULATION AND PERFORMANCE EVALUATION OF SELF-TEST AND POINT-OF-CARE IVD DEVICES
Self-test and rapid point-of-care IVD tests are increasingly being used for monitoring the health of European citizens. Manufacturers are responding to this market by designing devices for a widening range of health parameters. Although technological sophistication of these devices is increasing rapidly, reliable test results can only be obtained if device design and performance evaluations take into account the intended end user. Changing regulatory requirements must also be considered by manufacturers of such tests.
- Design considerations for self-test and point-of-care IVD devices
- Performance evaluation expectations by regulatory bodies
- Potential changes in regulatory requirements with revision of IVDD

Dr Ivor Barrett
IVDD Certification Manager, Medical Notified Body
UL INTERNATIONAL (UK) LTD

5:10 CONCLUSION OF DAY ONE
A GLOBAL PERSPECTIVE ON EVOLVING IVD REGULATIONS

EU IVD manufacturers need to maintain a broad focus and stay abreast of both local regulatory developments as well as key global regions, from well established regions like Canada to recently implemented regulatory systems such as Australia. The consultations for the recast of IVD will potentially bring the EU into line with many other regulatory regions with a shift towards a risk-based classification system; specifically the GHTF approach to update the current “high risk” system. As EU countries work tirelessly to develop a harmonized IVD classification system, it is important for EU companies to have a working knowledge of the regulatory similarities and differences taking place across the world, from the EU to Asia and the Middle East, to be ready to maximize their opportunities.

Sharon Williams
IVD Certification Manager
SGS UNITED KINGDOM LIMITED

HOME BREWED DIAGNOSTICS: GUIDANCE ON REGULATIONS & PERFORMANCE EVALUATIONS

Homemade or “home brewed” diagnostics are assays that are developed in laboratories and research centers utilizing analyte-specific reagents (ASRs). Home brewed diagnostics are considered products for “research use only” (RUS) in the EU and are not covered under the current IVD. While home brewed diagnostics have proved to be instrumental for physicians and scientists making important medical decisions, manufacturers have little guidance on how these will be regulated.

- Defining regulations for RUS products
- Home brew diagnostics and the recast of the IVD
- Highlighting resources for further clarity
- Analyzing FDA home brew regulations

Jonathan Day
Quality and Regulatory Manager
DNA ELECTRONICS

DEVELOPING DRUG & DIAGNOSTIC COMBINATION PRODUCTS IN THE EU

The healthcare industry has seen a rise in the prescription of combination products—multifunctional products manufactured from a mix of components to form a single product—due to new scientific and technological advancements over the past few decades. Combination products in the EU have multiple definitions found in various directives including the MDD and the AIMDD. The Global Harmonization Task Force (GHTF) is working toward developing a harmonized set of rules that will provide manufacturers with a clearer idea of combination product regulations in EU countries.

- Evidence requirements for drug and diagnostic combination products
- Best practices for obtaining regulatory approval with combination product
- Key areas of interest in GHTF’s combination product regulation proposal

Christian Fulda
Partner
JONES DAY

LOOKING INTO THE FUTURE OF EUROPEAN COMPANION DIAGNOSTICS & PERSONALIZED MEDICINE

Similar to combination products, companion diagnostics have seen a significant growth within the past few years. These tests provide information on an individual’s genetic and genomic characteristics that can potentially be used to make various treatment decisions in specific cases. With the discovery and validation of biomarkers, companion diagnostics look to have a strong future for manufacturers and patients alike. The challenge, however, stems from having little regulatory framework to follow.

- EU regulatory expectations of companion diagnostics
- Comparing regulatory requirements for companion diagnostics
- Forecasting the development of future regulations

Dr. Lisa Rice
Project Manager
QIAGEN
PREVIOUS CONFERENCE ATTENDEES INCLUDE:

DR. MAURIZIO SUPPO
Vice President, Standardization, Technology & Industry Affairs

Since April 2011 Dr. Maurizio Suppo is VP of Standardization, Technology and Industry Affairs at Siemens Healthcare, Erlangen – Germany, responsible for defining and driving standardization strategy & activities world-wide for all Siemens Healthcare products and coordinating interactions with the key industry trade associations. Awarded with his PhD in molecular biology (Magna cum Laude) from the University of Turin, Italy in 1985, he started his career in the diagnostic division of DiaSorin in the Regulatory and Product Validation Department. Later on he worked for the European diagnostic division of Becton Dickinson (Grenoble, France) as RA manager and later on took also responsibility for quality assurance for the whole of Europe, Middle-East and Africa becoming involved in standardization activities CEN TC 140 & ISO TC 212 and then elected chairman of the European Diagnostic Manufacturers Association (EDMA) Standardization Working Group.

Dr. Suppo has been a member of the board at RAPS (Regulatory Affairs Professionals Society) headquartered in Washington DC (2000-2003) an UNI expert in CEN TC 140 and ISO TC 212 and a Member of the Editorial Advisory Board of Medical Device Technology magazine. He is the chairman of the EDMA Medical Vigilance Task Force and the co-chair of the COCIR International Regulatory Affairs focus group.

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

ATTENDEE PROFILE:

Executives that will find this program of greatest applicability are those working within diagnostic corporations to commercialize new diagnostic tests though 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