PROGRAM OVERVIEW:

As diagnostic tests become more complex, offering faster, more effective and targeted testing opportunities, the challenges in assuring regulatory approval for these products increases in tandem. The diversity of test development and commercialization results in a challenging regulatory environment, and the rapid rate of new innovation has left the FDA and other regulators around the world challenged to keep pace with innovation. This annual conference program will bring together regulators as well as industry experts who will share and discuss the challenges that they have faced in bringing new tests to the market, as well as the strategies they have used to navigate through an uncertain and evolving regulatory environment.

At the forefront of importance during the program will be representatives from the FDA, who will provide insight on current and projected regulatory guidance and revisions. Understanding the FDA perspective and having an opportunity for frank dialogue with FDA Reviewers regarding specific challenges and scenarios will provide an unparalleled opportunity for conference participants. In addition, FDA regulatory experts will be accompanied by industry representatives who have successfully forged relationships with the FDA in order to bring new technologies to the market.

For many organizations, a clear challenge in the regulatory approval process is ensuring a strong platform of clinical data or evidence to work from. Designing studies that are adequate in not only the sample size, but also that are representative of the intended user is increasingly challenging, particularly for products that do not have comparators on the market. Presenters will provide the audience with case studies and strategies for developing thoughtfully designed clinical studies that will result in an adequate pool of data to be used for approval processes.

Overall, this comprehensive two-day program will bring together prominent diagnostic clinical and regulatory thought leaders from a variety of distinguished organizations to share lessons learned as well as expert practices and forward thinking solutions. This dynamic meeting will provide attendees, speakers, and sponsors with an ideal opportunity to network, knowledge share, and openly discuss challenges and opportunities surrounding clinical affairs and regulatory approvals for diagnostic tests.

DISTINGUISHED PRESENTERS INCLUDE:

Donald J. St.Pierre
Deputy Director for New Product Evaluation
OIVD, CDRH

Kimberly A. Trautman
Associate Director, International Affairs
CDRH, FDA

Sandy Perreand
Executive Director of Global Regulatory Affairs
BIOMERIEUX INC.

Fayyaz Memon
Vice President, Regulatory Affairs & Quality Assurance
PRIMERADX

Kalidip Choudhury, PhD
Senior Director, Business Development
THERMO FISHER SCIENTIFIC

Martin R. Mann
Senior Regulatory Affairs Manager
IMMUNODIAGNOSTICS,
THERMO FISHER SCIENTIFIC

William Clarke PhD, MBA, DABCC
Associate Professor of Pathology, Director, Clinical Toxicology Director, CPOCT
JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE

David Stivers
Senior Biostatistician
ALEREE

Lauren Silvis
Partner
SIDLEY AUSTIN LLP

Randy Prebula
Counsel
HOGAN LOVELLS US LLP

Jeff Gibbs
Counsel
HYMAN, PHELPS & MCNAMARA, P.C.

Philip T. Lavin, PhD
Executive Vice President, Device Programs
APTV SOLUTIONS

Wendy Rubinstein, MD, PhD
Director, NIH Genetic Testing Registry and Senior Scientist
NATIONAL INSTITUTES OF HEALTH

Mark A. Del Vecchio
Vice President, Regulatory Affairs
NANOSPHERE

Cathy Fomous, PhD
Office of Biotechnology Activities
NATIONAL INSTITUTES OF HEALTH

Nancy Maldeis, PhD, MPH, CCRA
Director, WW Corporate Clinical Operations / Corporate Clinical Operations
BD

Betty Stephenson
Director of Corporate Statistics and Clinical Data Management
BD

Terry Raich
Director of Clinical Affairs
NANOSPHERE

Marc Cromer
Head of Global Validation
LIFE TECHNOLOGIES CORP

Gail E. Radcliffe, PhD
Affiliate Principal Regulatory Consultant
APTV SOLUTIONS

Susan Rockwell
Corporate Brand Manager, Medical Devices
APTV SOLUTIONS

Jill Visor, MS, CCRA
Director, Clinical Research Services
NAMSA

Jennifer Mischke
Director of Biostatistics
NAMSA

Tom Tsakeris
President
DEVICES & DIAGNOSTICS CONSULTING GROUP, INC.
As a result of the recent FDA 510(k) draft guidance, many executives in the diagnostic industry are eager to better understand regulatory changes and how current and future revisions will impact the overall diagnostic approval process. With the release of “The 510(k) Program” document, the FDA has made it clear that it is standing strong behind the 510(k) process and is committed to ongoing improvement of the most common regulatory pathway. Although the released guidance documents are presently in draft form, it is essential for clinical and regulatory executives to have a concrete understanding of FDA submission expectations.

Donald J. St.Pierre
Deputy Director for New Product Evaluation
OIVD, CDRH

9:20 KEEPING CURRENT ON FDA MODIFICATIONS TO THE PRE-MARKET APPROVAL (PMA) PROCESS
In March of this year, the FDA issued informal guidance outlining key considerations in the pre-market review process, including a set of risks and benefits to be weighed by the agency. According to the FDA, the guidance “outlines the systematic approach FDA device reviewers take when making benefit-risk determinations during the premarket review process.” Considering the majority of Class III diagnostics require premarket approval, ensuring a firm understanding of the revised regulatory pathways for new diagnostic tests is critical in an atmosphere of increased market competition.

- Review of the new released draft guidance
- Understanding when PMA is truly necessary
- Comparing the PMA and 510(k) processes
- Avoiding potential pitfalls of the PMA

Donald J. St.Pierre
Deputy Director for New Product Evaluation
OIVD, CDRH

Fayyaz Memon
Vice President, Regulatory Affairs & Quality Assurance
PRIMERADEX

5:20 COFFEE & NETWORKING BREAK

3:10 OVERCOMING RIGOROUS REGULATORY HURDLES FOR INNOVATIVE MOLECULAR DIAGNOSTIC ASSAYS
Revolutionary molecular testing techniques are being developed for a wide range of applications including disease prediction, companion diagnostics, prediction of treatment efficacy, and personalized medicine. Due to the complex nature of these tests, there are significant clinical and regulatory challenges associated with these emerging molecular diagnostics. In light of innovation, the current regulatory landscape stipulates rigorous validation of new molecular diagnostic assays and clinical and regulatory executives are seeking more clearly defined guidelines by the FDA to help them gain clarity.

- Differentiating regulatory requirements - molecular vs. traditional diagnostics
- Conducting clinical trials for a molecular diagnostic test
- Exploring the future of molecular diagnostics

Randy Prebul
Counsel
HOGAN LOVELLS US LLP

1:30 CLINICAL AFFAIRS AND REGULATORY APPROVALS FOR DIAGNOSTICS

1:00 CHAIRPERSONS OPENING REMARKS

3:40 LEGAL PROCESSES AND SOLUTIONS WHEN SECURING DIAGNOSTIC REGULATORY APPROVAL
This session will focus on legal issues that may arise during the path to market, including appropriate application of 510(k) vs. PMA standards and changing requirements for clearance or approval. It will also discuss the appeals process, options for resolution of scientific and regulatory disputes, and other methods for constructive engagement with FDA.

Lauren Silvis
Partner
SIDLEY AUSTIN LLP

4:30 ROUND TABLE DISCUSSION: BEST PRACTICES IN WORKING WITH FDA REVIEWERS TO SECURE REGULATORY APPROVAL
In the past year, guidelines set forth by the FDA have gone through much transformation, leaving many clinical and regulatory executives with an unclear understanding of what FDA reviewers are truly looking for when reviewing regulatory submissions. Through open and transparent dialogue directly with a team of regulatory thought leaders and former FDA reviewers, attendees will have an opportunity to address common challenges and gain suggested best practices surrounding the submission, review and approval process for diagnostic tests.

MODERATOR:
Gail E. Radcliffe, Ph.D.
Affiliate Principal Regulatory Consultant
APTIV SOLUTIONS

PANELISTS:
Tom Tsakiris
President
DEVICES & DIAGNOSTICS CONSULTING GROUP, INC.

Jeff Gibbs
Counsel
HYMAN, PHELPS & MCNAMARA, P.C

Mark A. Del Vecchio
Vice President, Regulatory Affairs
NANOSPHERE

5:20 CLOSING REMARKS AND DAY ONE CONCLUSION
11:40 GROUP BREAKOUT SESSIONS

Whether your company is large or small, IVD or LDT focused, the breakout sessions will provide conference attendees with an opportunity to identify topics they wish to discuss further in smaller, more focused groups. Conference facilitators will take volunteer moderators from the audience to lead each discussion. Through the breakout sessions, all attendees, speakers, and sponsors are encouraged to become active participants to allow for better exchange of ideas, peer-to-peer learning, and open discussion.

12:30 LUNCHEON FOR ALL ATTENDEES, SPEAKERS AND SPONSORS

1:30 ACQUIRING SUITABLE SAMPLE POPULATIONS TO MEET CHANGING FDA GUIDELINES

Determining the appropriate sample size and specimens for clinical trials is one of the most important and challenging steps in the early development process. In recent years, many diagnostic companies have utilized the methodology of attaining the largest population and filtering accordingly, yet considering the new and pending FDA regulatory revisions, this method alone may not be acceptable. Looking ahead, clinical and regulatory executives must be aware of the sample size selection criteria and intended use in order to successfully complete early stage development, while meeting the revised regulatory requirements set forth by the FDA.

Terry Raich
Director of Clinical Affairs
NANOSPHERE

8:50 ENSURING PRECISE DATA COLLECTION DURING DIAGNOSTIC CLINICAL TRIALS

Developing a diagnostic test can take many years, from the initial biomarker discovery to a successful commercial launch. During the development process, the clinical patient samples play a key role and as data requirements continue to increase, accurate data collection is imperative. Any discrepancies found in clinical data could hinder the timeframe in which a product secures regulatory approval and goes to market, becoming extremely costly and time consuming for a diagnostic company. It is vital for clinical and regulatory executives to maximize their efforts early on in the trial design process by following a strong clinical data collection method.

• Utilizing a statistical methods to decide sample size
• Key factors affecting sample population determination
• Recognizing quantity vs. quality

Nancy Maleideis, PhD, MPH, CCRA, Director, WW Corporate Clinical Operations / Corporate Clinical Operations

9:40 COFFEE & NETWORKING BREAK

10:00 USING A RISK-BASED APPROACH TO ENSURE DATA QUALITY IN IVD CLINICAL STUDIES

As the development of diagnostic tests becomes increasingly complex and innovative, there is an evolving expectation of substantial clinical data to support regulatory approval. As a critical body of evidence, it is essential that study data be collected in a manner that results in high-quality, valid data. The new FDA guidance on a risk-based approach to monitoring provides an opportunity to ensure the integrity of the study data, while gaining speed and efficiency in performing on-going data monitoring. Particularly when coupled with electronic database systems, a risk-based monitoring approach allows for the earlier detection of potential issues, saving both time and resources during the conduct of the clinical trial.

• Statistical Plans: What does the FDA look for?
• Common errors in statistical analysis
• Assuring the integrity and reliability of clinical data

Jill Visor, MS, CCRA, Director, Clinical Research Services
NAMSA

Jennifer Mischke, Director of Biostatistics
NAMSA

10:50 PANEL DISCUSSION: EXPLORING THE USE OF ADAPTIVE DESIGNS FOR IVD CLINICAL TRIALS

A well designed adaptive trial enables sponsors to respond to clinical data collected during a trial and plan for modifications as needed. For diagnostics, this is best achieved by re-focusing the trial in a way that maximizes the impact of each subject’s contribution. In order to execute an adaptive trial design, it is important for clinical and regulatory executives to understand the role that technology plays in support of adaptive design implementation. Technology within adaptive clinical trials provides clinical teams with real-time information, enabling clinicians with quick and seamless alterations in response to information.

MODERATOR:
Susan Rockwell, Corporate Brand Manager, Medical Devices
APTV SOLUTIONS

PANELISTS:
Marc Cromer, Head of Global Validation
LIFE TECHNOLOGIES CORP

David Stivers, Senior Biostatistician
ALERE

Philip T. Lavin, PhD, Executive Vice President, Device Programs
APTV SOLUTIONS

2:20 SUCCESSFULLY SECURING REGULATORY APPROVAL BY OVERCOMING PITFALLS IN STATISTICAL ANALYSIS OF CLINICAL TRIALS

Increasingly complex diagnostic tests require a substantial amount of clinical evidence in order to secure regulatory and reimbursement approvals. Diagnostic companies are faced with tremendous challenges in conducting trials, acquiring test samples, producing data and navigating through uncertain regulatory pathways. As a result, executives are seeking more clearly defined guidelines by the FDA surrounding sufficient clinical data and statistical analysis when securing approval for diagnostic tests.

• Common errors in statistical analysis
• How Dx is different from Pharma
• Statistical Plans: What does the FDA look for?

Betty Stephenson
Director of Corporate Statistics and Clinical Data Mgmt
BD

3:10 THE NIH GENETIC TESTING REGISTRY: ENHANCING OVERSIGHT THROUGH TRANSPARENCY

The National Institutes of Health (NIH) launched the Genetic Testing Registry (GTR) in February 2012 to help clinicians navigate the rapidly changing landscape of genetic tests. The GTR provides in-depth information about genetic tests that is voluntarily submitted by test providers. It also serves as a portal to other medical genetics information, such as practice guidelines and a variety of genetic, scientific, and literature resources available through the NIH National Library of Medicine. This session will explore the oversight and clinical dimensions of the GTR.

• GTR overview: purpose, scope, and goals
• Oversight role of the GTR
• Demonstration of the GTR: content and navigation
• Assuring quality of the information in the GTR

Cathy Fomous, Ph.D.
Office of Biotechnology Activities
NATIONAL INSTITUTES OF HEALTH

Wendy Rubinstein, MD, PhD
Director, NIH Genetic Testing Registry and Senior Scientist
NATIONAL INSTITUTES OF HEALTH

4:00 CLOSING REMARKS & CONFERENCE CONCLUSION

DAY TWO / TUESDAY, SEPT. 11 / CLINICAL AFFAIRS AND REGULATORY APPROVALS FOR DIAGNOSTICS
ATTENDEE PROFILE:

Executives that will be most interested in participating in this conference program will be those involved in securing regulatory approval through conducting clinical research for diagnostic tests. Job titles of executives that will be most applicable for this program include VPs, Directors and Managers of:

- Regulatory Affairs / Regulatory Operations
- Clinical Trials / Clinical Operations
- Medical Directors / Medical Affairs
- Chief Medical Officers
- Chief Scientific Officers

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:

- Clinical Research Organizations (CRO)
- Regional Clinical Consultancies
- Regulatory Consultants
- Electronic Clinical Trial Consultants
- Health Economics & Outcomes Researchers
- Data Management / Software Providers

PREVIOUS ATTENDEES INCLUDE:

VP Global Regulatory & Clinical Affairs, Alere
Director of Biostatistics & Clinical Data Management, Alere
Regulatory Affairs Manager, Aniara Diagnostica
Senior Director of Medical Clinical, Regulatory, Asuragen
VP of Regulatory Affairs, Atherotech Diagnostic Laboratory
Clinical Studies Manager, Axis Shield Diagnostics
VP Corporate Regulatory Affairs & Compliance, BD
Director, Clinical Operations, BD
Director of Worldwide Corporate Clinical Operations, BD
Director of Regulatory & Clinical Affairs, Biodesix, Inc.
Corporate Vice President, BioMed Diagnostics
Executive Director Global Regulatory Affairs, BioMerieux
Regulatory Affairs Representative, Bio-Rad
Clinical & Regulatory Coordinator, Boule Medical AB
Director of Regulatory Affairs & Quality Assurance, Capnia
Director, Clinical Operations, Capnia
Chief Scientific Officer, Caris Life Sciences
Quality Assurance Manager, Cellavision AB
Director of Clinical Affairs, Cepheid
Compliance Director, Cepheid
Director of Quality Systems, Cylex Incorporated
Clinical & Scientific Research Manager, Diagnostica Stago
Senior Manager of Regulatory Affairs, DiaSorin
VP Operations, Quality & Regulatory Affairs, DNA Genotek
Senior Advisor, Diagnostics, Eli Lilly & Company
SVP Product Development, Exagen Diagnostics
Associate Director for Clinical Studies, OIVD, CDRH, FDA
Scientific Reviewer, Microbiology Division, OIVD, CDRH, FDA
Associate Director of Science & Technology, OIVD, CDRH, FDA
Director of Clinical Affairs, Fujirebio Diagnostics
Clinical Compliance Manager, Gen-Probe
Regulatory Affairs, Genzyme Corporation
Senior Director of Clinical Research, Histox, Inc.
Director of Regulated Products, Idaho Technology
Quality Assurance & Regulatory Affairs, Immunocor
Senior Scientist, INOVA Diagnostics
VP Quality Assurance & Regulatory Affairs, IRIS
Dir Regulatory Affairs Companion Diagnostics, J&J
Director, Clinical Microbiology Laboratory, Lahey Clinic
Head of Global Validation, Life Technologies Corp
Director of Regulatory Affairs, Luminex Corporation
Director of Regulatory Affairs & Trade Compliance, Millipore
VP Regulatory Affairs & Quality, Nanosphere
Vice President of Clinical & Regulatory Affairs, Nodality Inc
Director of Regulatory Affairs, Novartis Molecular
Manager of Regulatory Affairs, Lambda
Manager Regulatory Affairs, Ortho-Clinical Diagnostics
VP, Regulatory Affairs & Quality Assurance, PrimeraDx
Associate Director of Regulatory & Clinical Affairs, Qiagen
Head of Clinical Research, Radiometer Medical ApS
CMO, Rapid Pathogen Screening
Director of Regulatory Submissions, Roche Diagnostics
VP Regulatory Affairs, Siemens Healthcare Diagnostics Inc.
Chief Medical Officer, Somalogic
Manager of Regulatory Affairs, Somalogic
Vice President, Technology, SQI Diagnostics Systems Inc.
Director of Regulatory & Quality Affairs, Stago
Vice President, SysnapDx Corp.
Director of Clinical Affairs, Sysmex America
President, Trillium Diagnostics, LLC
Vice President of Clinical Operations, Veracyte
Sr. Director of Quality & Regulatory Affairs, Verinata Health
Head of Regulatory Affairs, 454 Life Sciences/Roche

... AND MANY MORE!