AND KENX HAVE JOINED FORCES TO DELIVER AN INCREDIBLE LEARNING EXPERIENCE

Attend Virtually or In-Person

ANALYTICAL PROCEDURES & METHODS VALIDATION

LABORATORY DATA INTEGRITY COMPLIANCE CONGRESS

June 22-24, 2021 | The Dana Mission Bay | San Diego, CA

KEYNOTE SPEAKER

Analytical Procedure Lifecycle Management / Validation, Verification, and Transfer of Analytical Procedures

Horacio N. Pappa, CQE, Ph.D., Director – General Chapters, Global Science and Standards Division, **U.S. Pharmacopeia**

33 HOTTEST TOPICS ADDRESSING TODAY'S GMP LABORATORY, INCLUDING:

ANALYTICAL PROCEDURES & METHODS VALIDATION

- USP General Chapter <1220> Analytical Procedure Lifecycle Management
- Risk-Based Development and Validation of Test Methods
- System Suitability Tests (SST) and Method Performance Monitoring
- Regression Analysis for Instrument Calibration Curves
- Continued Method Performance Verification – An Effective Approach
- Development and Validation of Stability-Indicating Analytical Methods
- OOS/OOT Investigation in Analytical Testing
- A Useful Strategy for Analysis of Dissolution Profiles
- Apply QbD Principles in Analytical Procedures
- Method Variation – Handle Measurement Uncertainty

LABORATORY DATA INTEGRITY COMPLIANCE

- Overcome Top Five Challenges in the GMP Laboratory
- Manage Regulatory Inspections and Respond to Findings
- Identify Root Cause and Implement Corrective Action
- Learn Data Quality Considerations in the Method Development
- Graph and Analyze Clean Data for Decision Making
- Conquer DI by Minimizing Human Error
- Create Quality Cultures that Identify and Address Risks
- QC Audit Trails – Implement Routine Auditing
- Benefits and Importance of Process Mapping
- Statistical Method to Analyze Data Of Validation Test Results

20 LEADING SUBJECT MATTER EXPERTS SHOWCASING BEST-IN-CLASS INNOVATION AND PROCESSES, INCLUDING:

Kim Huynh-Ba, Managing Director, **Pharmalytik**; Adjunct Professor, Regulatory Compliance, **Illinois Institute of Technology (IIT)**

Geoff Carr, Ph.D., Director, Analytical Development, **Patheon**, part of **ThermoFisher Scientific**

John Long, Ph.D., Director, Bioanalytical Method Development and Validation, **Aldevron**

Raul Soto, Senior Principal Software Quality Engineer, **Johnson & Johnson Vision Care**

AND MANY MORE – SEE INSIDE FOR DETAILS

SEND YOUR TEAM! THIS EVENT IS CO-LOCATED WITH:

STABILITY TESTING & PROGRAM MANAGEMENT

Register Online | www.kenx.org/conferences/laboratory-university-2/

Day One – June 22, 2021

12:00 PT **Exhibitor Showroom & Virtual Platform Open House**

1:00 PT **Chairman's Opening Remarks**

1:15-2:00 PT Analytical Procedure Lifecycle Management / Validation, Verification, and Transfer of Analytical Procedures

Horacio N. Pappa, CQE, Ph.D., Director – General Chapters, Global Science and Standards Division, **U.S. Pharmacopeia**

DESCRIPTION TO COME

2:00-2:45 PT Develop a Roadmap for the Lifecycle Management of Analytical Procedures

Kim Huynh-Ba, Managing Director, **Pharmalytik LLC;** Adjunct Professor, Regulatory Compliance, **Illinois Institute of Technology (IIT)**

- Understand the Regulatory Requirements of the Analytical Procedure
  - » analytical testing to support pharmaceutical quality systems
  - » FDA expectations based on ICH and USP guidelines
  - » future needs for the development of the new ICH Q14 analytical Lifecycle and the revision of ICH Q2(R1)
- Lifecycle Management of Analytical Methods
  - » discuss the deficiencies of ICH Q2 and USP <1225>
  - » understand the USP lifecycle management concept <1220>
  - » establish method development goals by QbD
  - » evaluate validation parameters for analytical procedures
- Establish System Suitability and Monitor Method Performance
  - » evaluate critical changes that could impact the validity of the analytical testing
  - » trending system suitability for measuring method performance
  - » perform periodic reviews using a risk-based approach

3:00 - 3:30 PT Exhibitor Showroom & Think Tank Session
Ensure Your GMP Lab is Inspection Ready

3:45-4:30 PT Data Integrity in the GMP Lab – Overcome Top 5 Challenges

Robert J. Wherry, Principal, **White Birch Consulting Services**

Part 1 – Inspection Challenges

- The current focus for inspections
- Understand the agency mindset for inspections
- Agency expectations for agency inspections
- Agency tools for compliance
- Using risk to focus efforts & resources

Part 2 – Establish and Maintain Inspection Readiness

- Functional compliance self-assessments
- An internal audit program and internal audits for inspection readiness
- Mock inspections
- Inspection readiness as a value add and company mindset

Part 3 – Handling Inspections

- A vision for a perfect inspection: the ideal state
- Remediation when issues are found (because no one is perfect)

Knowledge Exchange

Attendees take part in an exercise in preparing for an Agency inspection.

Takeaway Tools

- Checklists for a Laboratory Inspection Plan, including extensive Data Integrity topics

4:30-4:15 PT Creating a Quality Culture

Matthew LaPierre, Data Integrity Lead Consultant, **Jackson Scott Consulting**

- Identify what makes a good Quality Culture
- Learn the not-so-evident characteristics of a bad Quality Culture – Signs and concerns
- Understand leadership's incredible responsibility
- Review real-life examples of how companies have improved Quality Culture
- Learn to shift your thinking when it comes to Quality Culture

Takeaway Tools

- Real life examples of how to improve Quality Culture at your organization

5:30 PT **Game Night - Trivia Welcome Reception**

Day Two – June 23, 2021

07:00 PT Exhibitor Showroom Opens

7:15 – 8:00 PT **Select Between Knowledge Exchange Sessions**

Analytical | Risk-based Development and Validation of Test Methods

John Long, Ph.D., Director, Bioanalytical Method Development and Validation, **Aldevron**

- Use the lifecycle approach to method development and validation
- Analytical Target Profile to define key parameters to ensure fit-for-purpose methods
- When is good enough good enough – Keys to phase-appropriate validation strategies
- Robustness, robustness, robustness
- Set phase-appropriate acceptance criteria for qualification and validation
- Address regulatory compliance for non-GMP method development activities.
- Use the pre-validation model to de-risk validation execution

Takeaway Tools

- Analytical Target Profile worksheet
- List of useful references

Data Integrity | Learn How to Graph and Analyze Data for Decision Making

Raul Soto, Senior Principal Software Quality Engineer, **Johnson & Johnson Vision Care**

- How human perception affect the way our brains interpret different kinds of graphs
- Common types of errors in graphs, and how to avoid them
- Select the most effective graph type to display and analyze your data in various scenarios:
  - comparisons of two or more data sets
  - proportional data
  - display error bars and p-value comparisons
  - trends – data as a function of time
  - contour, surface, and radar / spider plots to display and analyze multivariable / multidimensional data
  - scatter diagrams and SPLOM matrices to discover correlations between multiple variables
  - frequency-based data
  - color-based heat maps

8:15 – 9:45 PT **Select Between Knowledge Exchange Sessions**

Analytical | Establish Test Parameters, Conditions and Acceptance Criteria for Analytical Measurements

Steven S. Kuwahara, Ph.D., Principal Consultant, **GXP BioTechnology**

Part 1 – Test Parameters and Conditions

- Determine what should be your critical test parameters
  - Critical Quality Attributes (CQA) and Critical Process Parameters (CPP) for the analytical measurement
  - know what attributes and parameters can affect the analytical measurement
  - Decide on conditions for the analytical measurement
  - criticality of an attribute or parameter
  - how the acceptance criteria will be affected by the conditions
- Provide data on the criticality of attributes and parameters
  - use statistical methods on attributes and parameters

Part 2 – Acceptance Criteria

- Early-stage measurements to use in determining acceptance criteria
  - estimate the criticality of a measurement
  - decide on the limits of acceptance
- Determine acceptance criteria before a test method validation
  - the validation study should confirm the acceptance criteria
- Methods for setting the limits of acceptance criteria
  - types of limits employed at different stages of method establishment
- Use QC samples and control samples
  - setting limits on acceptance criteria of control samples
- Decide on the acceptability of a test result
- Use attributes and variable test results

Knowledge Exchange

Participants are walked through the establishment of a new analytical test measurement.

Data Integrity | Rethinking Your Approach to Technology

Matthew LaPierre, Data Integrity Lead Consultant, **Jackson Scott Consulting**

Part 1 – The Importance of Technology to the Pharma Industry

- Learn the importance of industrial revolutions to our focus on current technological advancements in computerized systems
- Understand historical thinking to technology in the pharma industry
- Review examples of problematic computerized systems with data integrity limitations we use today
- Learn the role Pharma 4.0 will play in enhancing Data Integrity controls

Part 2 – The New Approach to Technology

- Understand the importance of interconnectivity
- Minimize the amount of audit trail reviews by implementing appropriate software solutions
- Learn to use technology as an enabler and component of big data practices
- Identify real technological solutions to computerized systems that will enhance Data Integrity controls

Knowledge Exchange

Attendees take part in a round-the-room conversation comparing real life DI challenges in technology.

Takeaway Tools

- Examples of real-life DI challenges in technology and what we can do to improve

10:00 - 10:30 PT Exhibitor Showroom & Think Tank Session

Method Variation - Handling Measurement Uncertainty

10:45 – 12:15 PT **Select Between Knowledge Exchange Sessions**

Analytical | Case Study – Implementation, Validation and Lifecycle Management of Analytical Procedures

Bette Monnot-Chase, Director, Analytical Sciences, **Marinus Pharma**

Part 1 – Method Development – Trouble-Shooting New Peaks Observed During Routine Use

Method evolution with third party vendor can be challenging. This case study looks the need for solid scientific oversight of analytical testing at third party vendors. We will look at the history of a method used for assay and related substance testing a product formulation through the phase of development.

- Point to remember – Method development is not 'once and done' in most cases
- What constitutes a method issue – Getting your partner to engage in the analysis
- Process impurities in the drug product – The devil is in the details
- Identifying sources of new peaks
- Dealing with method artifacts
- Understanding validation robustness

Part 2 – Case Study of the Process Impurity that Grows

This case study involves an API process impurity that is not present on the vendor COA but is detected in the analysis of the API at the drug product manufacturer. Resolution employs use LC-MS to deconvolute co-eluting peaks.

- Discuss the value of communication and establishing expectations
- Revisit understanding the strength and weakness of the method use
- Look at the importance of tangential methods
- Understanding the value of the right laboratory for the problem at hand

Knowledge Exchange

Attendees take part in a round-the-room survey of their company's approach addressing method issues encountered during product development. Develop a list of potential approaches to resolve method deficiencies.

Takeaway Tools

- Understanding factors contributing to method lifecycle management
  - » Common source of undesired peaks
  - » Identify method versus product related
- A list of approaches to evaluate 'extra' peaks
- An appreciation for the value for tangential methods

Data Integrity | Identify Root Cause and Implement Corrective Action

Robert J. Wherry, Principal, **White Birch Consulting Services**

Part 1 – Root Cause Analysis (RCA)

- RCA basics
- RCA advanced techniques
- DI issues versus OOS/OOT issues
- Agency guidance

Part 2 – Remediation & Corrective Actions

- FDA's remediation approach
- Other agency approaches to remediation
- The key to effective corrective actions

Part 3 – Case Studies – Lots of Them

- Group discussions on the way to address a Data Integrity issue
- A recommended remedy

Knowledge Exchange

Attendees take part in case study exercises determining root causes and effective corrective actions for Data integrity Issues.

Takeaway Tools

- Techniques for Data Integrity Root Cause Analysis
- Checklists for remediation of data integrity issues

12:30 - 1:15 PT **Select Between Knowledge Exchange Sessions**

Analytical | **Establish System Suitability and Monitor Method Performance**

Steven S. Kuwahara, Ph.D., Principal Consultant, **GXP BioTechnology**

- What is System Suitability?
- Definition of System Suitability Tests (SST)
- How and When SST is used
- Using control samples
- Deciding on what should be employed as SSTs
- Deciding on acceptance limits for SST results
- Examples of SST for various tests that produce attribute results and variable date
- Monitoring SST results as criteria for test method performance

Takeaway Tools

- Methods for setting up control charts for attribute and variable data
- White Paper on Why SST is not a substitute for Analytical Instrument Qualification (AQI)

Data Integrity | **Data Quality Considerations that Survive the Method Lifecycle**

Kevin Walsh, Senior Director, **Azzur Labs**

- Modernize analytical methods that achieve data quality
- Data quality considerations in method development
- Common lapses and how to minimize them
- Tools to access data quality and data integrity risk
- Continuous improvement – Quality cultures that identify risk

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1:30 - 2:00 PT Exhibitor Showroom & Think Tank Session
Data Integrity Process Mapping

2:15 – 3:45 PT **Select Between Knowledge Exchange Sessions**

Analytical | **Validation, Verification, and Transfer of Analytical Methods**

John Wass, Director, MSAT and Validation, **Xellia** *(Invited)*

DESCRIPTION TO COME

Data Integrity | **Conquer Data Integrity by Minimizing Human Error**

Steve Thompson, Director Industry Solutions, **ValGenesis**

Part 1 – Data Integrity And Human Beings

- The truth about data integrity
- The spectrum of human errors
- Adverse impact of errors
- Is removing people from processes the answer?

Part 2 – Conquering Data Integrity

- Process mapping is critical
- People versus systems
- The role of technology controls
- Quality by Design
- Quality by Review

Knowledge Exchange

Attendees participate in an open discussion and Q&A with attendees, and a live poll to be analyzed by all at end of presentation.

4:00 - 4:30 PT Exhibitor Showroom & Think Tank Session
Apply QbD Principles to Analytical Procedures

4:45 – 6:15 PT **Select Between Knowledge Exchange Sessions**

Analytical | **Control *N*-Nitrosamine Impurities in Pharmaceutical Products**

Geoff Carr, Ph.D., Director, Analytical Development, **Patheon, part of Thermo Fisher Scientific**

Part 1 – Introduction

- Understand the nature of *N*-Nitrosamine impurities and how they are formed
- Review the history that led to regulatory concerns with Sartans, Ranitidine and Metformin products
- The impact now on all other pharmaceuticals

Part 2 – Risk Analysis

- Learn the requirements for conducting risk analyses for currently marketed pharmaceutical products
- How to address risk analyses for all ingredients that go into a product
- Discuss some risk analysis examples o Importance of application of good chemistry for reliable risk analysis reports
- Understand the follow ups that may be required as a result of risk analyses

Knowledge Exchange

Participants are invited to share their experiences of working with risk analyses and their follow ups for nitrosamine.

Data Integrity | **Use Process Mapping to Identify Gaps**

Steve Thompson, Director Industry Solutions, **ValGenesis**

Part 1 – Process Mapping

- Setting the stage for process mapping
- Timing – When to create process maps
- Socializing process maps for clarity
- Guidelines – Setting standards and integrating

Part 2 – Audit Trail Review for Exceptions

- Human perspective
- System perspective
- Hybrid perspective
- Closing gaps

Knowledge Exchange

Attendees participate in an open discussion and Q&A with attendees, and a live poll to be analyzed by all at end of presentation.

6:15 PT **Close of Day Two**

Day Three - June 24, 2021

7:00 PT Exhibitor Showroom Opens

7:15 – 8:00 PT **Select Between Knowledge Exchange Sessions**

Analytical | **Regression Analysis for Instrument Calibration Curves**

Raul Soto, Senior Principal Software Quality Engineer, **Johnson & Johnson Vision Care**

Part 1 – Design, Execute, and Interpret Regression Analysis for Instrument Calibration Curves

- How to use linear regression to construct a mathematical model that allows us to predict the absorbance as measured by a spectrophotometer as a function of the concentration of a substance in a sample

Part 2 – Improve your Regression Analysis

- Use Goodness-of-Fit coefficients to evaluate how well does the regression model fit the data
- Verify that your regression model meets the assumptions of normality, homogeneity, and independence by using tools such as normality tests and residuals analysis
- Determine if specific data points are true outliers using standardized residual.
- Determine the concentration of a substance based on the calibration curve, within a given confidence range, using prediction intervals
- Discuss the concepts of blocking, masking, and randomization, and how they affect your regression analysis
- Interpret your model when the intercept of your calibration curve not zero, and what does this mean in the real-world

Data Integrity | **Audit Trail Review – Implement Routine Monitoring**

Loganathan Kumarasamy, Validation Consultant, **Zifo RnD Solutions**

- Understand why audit trail review is necessary – Examples and case studies
- Define business audit trail process and functional audit trail process
- Define audit trail review program as part of routine monitoring
- Risk based audit trail review process
- Recommendations and tips on how periodic audit trail review can be conducted
- Automation process in audit trail review

8:15 – 9:45 PT **Select Between Knowledge Exchange Sessions**

Analytical | Continued Method Performance Verification - An Effective Approach

Ronald D. Snee, Ph.D., Founder and President, **Snee Associates, LLC.**

Part 1 – Method Performance Verification – Purpose and Tools

- Importance and need to improve measurement Data Integrity and quality
- Role of continued verification of measurement systems
- Importance of understanding analytical variation
- Improve measurement process stability - Reduce measurement risk
- Measurement quality - Repeatability and reproducibility
- Improve test method robustness

Part 2 – Continued Method Performance Verification - A Systems Approach

- Need for systems approach to control and reduce variation and risk
- Framework for improving measurement process stability
- Use of control/reference samples and product stability data
- Organization for continued measurement process verification – Management's role
- Use of trending and other graphical methods to visualize and understand variation
- Tips and traps - What to watch out for

Takeaway Tools ⚒

- An article by Ronald D. Snee, "Risk-Based Continued Method Performance Verification System", Pharmaceutical Engineering, to appear in 2021
- Numerous case studies and examples of test method performance verification

Data Integrity | Manage Data Integrity Inspections and Respond to Findings

Peju Odunusi, Ph.D., Owner, **PJ Pharmaceutical Consulting LLC**

- Understand the importance of developing a Data Integrity mindset in your company
- Develop a company-wide audit preparation strategy
- Discuss steps needed to prepare for a successful audit
  - » emphasis on general audit readiness
  - » emphasis on data management audit readiness
- Discuss how to respond to audit findings

Takeaway Tools ⚒

- Audit checklist

10:00 - 10:30 PT Exhibitor Showroom & Think Tank Session
Understand the Human Impact in the QC Laboratory

Challenge Your Inventory Systems for Maximum Benefit and Minimal Issues

10:45 – 12:15 PT **Select Between Knowledge Exchange Sessions**

Analytical | Investigate OOS/OOT in Analytical Testing

Erin Thane, Vice President, **Azzur Labs**

Part 1 – Understanding the OOS/OOT/OOE

- Compliance intelligence – FDA expectations and recent Warning Letters
- OOS/OOT/Unexpected results examples
- Understand what triggers investigations
- Common deficiencies and minimizing OOS
- The impact of human error

Part 2 – Conducting the Investigation

- Develop an execution plan
- Establish risk-based Critical Quality Attributes (CQA)
- Identify root cause and implement corrective action
- Documentation best practice
- Investigation disposition and investigation reports

Data Integrity | Selection and Qualification Laboratory Instrumentation – Implement a Risk Assessment and Data Integrity Strategy

David W. Vincent, MPH, Ph.D, CEO, **VTI Life Sciences**

Part 1 – Introduction

- » Components of Data Integrity and quality integration
- » Quality Control check samples
- » system suitability test
- » analytical method validation
- » laboratory equipment validation and qualification

Part 2 – Equipment (Instrument) Categories

- How to categories laboratory instruments-based on a risk bases approach
  - » User Requirements Specification (URS)
  - » current trends in compliance issues noted with equipment.
  - » how to classify instruments and justify level of qualification
  - » Laboratory Equipment Validation and Qualification Process
    - ◊ Design Qualification (DQ)
    - ◊ Installation Qualification (IQ)
    - ◊ Operational Qualification (OQ)
    - ◊ Performance Qualification (PQ) and/or User Acceptance Testing (UAT)

Part 3 – Software Validation – Data Integrity – Change Control

- Processing software, instrument control, data acquisition, and report integrity
- Changes to qualified instruments and implementation of changes
- Change control process – Assessment, execution, and documentation

Part 3 – Maintaining Validated State (Life Cycle Approach)

- Calibration, preventative maintenance, and revalidation

12:30 - 1:15 PT **Select Between Knowledge Exchange Sessions**

Analytical | **Documentation and Revalidation Strategies after Method Changes**

John Long, Ph.D., Director, Bioanalytical Method Development and Validation, **Aldevron**

- Use the lifecycle approach to method validation is a regulatory expectation
- Implement a system to effectively communicate changes that could impact validation status
- Evaluate method changes against the original validation documents
- Understand that not all changes require re-validation
- Continuous monitoring of method performance
- Periodic method review (methods can change over time, whether you want them to or not)
- Change control to document supplemental validation activities associated with method changes

Takeaway Tools

- Checklist of steps for change management
- List of useful references

Data Integrity | **Develop a Training Program for the QC Scientist**

Lina Patel, Director, Quality Control, **Catalent Cell and Gene Therapy**

- Implement a robust training program tailored to lab personnel
- Create a Quality Culture to reduce risk
- Quickly identify lapses and implement correction action
- Conduct quality audits for continuous monitoring
- Ensure your lab is inspection ready

1:30 - 2:00 PT Exhibitor Showroom & Think Tank Session
Evaluate Method Validation Factors with Simple Statistical Methods

2:15 – 3:45 PT **Select Between Knowledge Exchange Sessions**

Analytical | **A Useful Strategy for the Analysis of Dissolution Profiles**

Ronald D. Snee, Ph.D., Founder and President, **Snee Associates, LLC.**

Part 1 – Available Methods and Tools

- Profile characteristics – Level and shape
- Effective use of graphical techniques
- Available methods – Strengths and limitations
- Profile linearization – A new useful approach
- A strategic approach that integrates the tools

Part 2 – Experiences in Using the Linearization Approach

- Analysis of results from a 3x3 factorial experiment
- Comparison of profiles generated by different apparatuses
- Creating and using profile specifications
- Identifying atypical profiles
- Tips and traps - What to watch out for

Takeaway Tools

- Article by Ronald D. Snee, "A Strategy for the Analysis of Dissolution Profiles" Pharmaceutical Engineering, July/August 2019, 49-59.
- Numerous case studies and examples of test method performance verification

Data Integrity | **Cultivate the Culture of Integrity in Data Management**

Peju Odunusi, Ph.D., Owner, **PJ Pharmaceutical Consulting LLC**

Part 1 – History and Trend in Data Integrity

- Review the US generic drug scandal in the 80s and its impact on the drug approval oversight
- Discuss recent inspection trend in the global pharmaceutical market
- Focus on 483s and warning letters related to Data Integrity in the last decade
- Key data management audit topics from regulatory agencies
- Steps to avoid pitfalls of poor data management

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Pharmaceutical Stability Discussion Group

Part 2 – Establish a Culture of Integrity in Data Management

- Elements of Data Integrity program
- Practical ways to build infrastructure for good data management
- Good documentation practices and change control – Electronic vs. paper record
- 21 CFR Part 11 and influence on audit trail
- Back-up and archival processes
- Implementation of system for corrective and preventive actions
- Continuous improvement through regular internal audits

Knowledge Exchange

This discussion focuses on 5 crucial FDA warning letters, covering various areas of data management. Attendees evaluate how the warning letters could have been avoided in light of the topic just discussed and Corrective and Preventive Actions to be implemented to fix the issues.

Takeaway Tools

- Summary list of the presentation/topic for easy reference
- Data management audit checklist

3:45 PT Afternoon Refreshment Break

4:00 – 5:30 PT Select Between Knowledge Exchange Sessions

Analytical | Validation and Development of Stability-Indicating Methods

Peju Odunusi, Ph.D., Owner, **PJ Pharmaceutical Consulting LLC**

Part 1 – Development of Stability-Indicating Methods

- What is a stability-indicating method?
- The importance of a stability-indicating method
- Stage approach in developing an HPLC method
- Challenges in developing a stability-indicating method
- Stress testing and forced degradation as tools for validating stability indicating methods
- Stress testing conditions for drug substance and drug product
- Final optimization step of HPLC method development
- Documentation practices

Part 2 – Validation of Stability-Indicating Methods

- Guidelines for analytical method validation
- Phase appropriate method validation
- Generating a validation protocol for registration submission
- Validation parameters to satisfy stability indicating power of a method
- Validation report documentation
- Method transfer process and expectations

Knowledge Exchange

Participants share ideas on how phase appropriate method validation was conducted on a finished product.

Data Integrity | Learn Statistical Methods to Analyze Data of Validation Test Results

Raul Soto, Senior Principal Software Quality Engineer, **Johnson & Johnson Vision Care**

Statistics in process validation has become a key topic since FDA released their 2011 Process Validation Guidance. In this session you will learn some of the key statistical tools that are used for validating manufacturing processes in the biopharmaceutical and medical devices industries:

Part 1 – Core Concepts

- Why are Statistics important in the biopharma/medical devices world?
- Quantitative vs Qualitative data

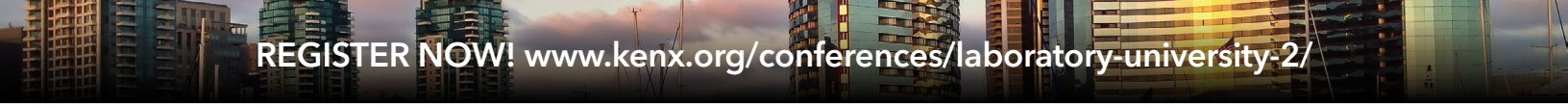
Part 2 – Does Your Product Meet Specs? Releasing Product or Validation Lots

- Quantitative data
  - » Process Capability Analysis
  - » normality testing
  - » variation – common vs. special cause, shifts and drifts
  - » tolerance intervals – an alternative to CPKs
- Qualitative data
  - » Acceptance Sampling Plans

Part 3 – Validating Changes to A Process – Hypothesis Testing

- t-tests for quantitative (variables) data
- Fisher's Exact test for qualitative (attributes) data

5:30 PT Close of Conference



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