

- **8:00 AM - 8:30 AM** Introduction Duncan Low, Amgen, Inc

- **8:30 AM – 10:00 AM** **Status of PAT Today**
 - Regulatory Status Duncan Low, Amgen
 - Developing standards and practices David Radspinner, Thermo
 - International perspectives Jan Gustafsson
 - Recent conference highlights tbd

- **10:00 AM – 10:15 AM** Break

- **10:15 AM - 12 Noon** **Practical Approaches**
 - Statistical treatment for large sample sizes – Joep Timmermans, Pfizer
 - Biologics vs. small molecules – Sangheeta Sagar, Merck & Tina Larson, Genentech

- **12 Noon - 1:30 PM** Lunch



- **1:30 PM - 3:00 PM PAT and Quality by Design (QbD)**
 - Interface with QbD Chuck Kettler, Eli Lilly
 - Validation in the new paradigm tbd
 - (We may not need to 3-peat lots for the regulators, but what do we need to do to satisfy ourselves?)

- **3:00 PM – 3:15 PM Break**

- **3:15 PM – 4.45 PM Benchmarking & preparation for FDA teleconference**
 - Introduction to benchmarking Steve Doherty, Lilly
 - Gathering questions for the FDA Duncan Low, Amgen
 - Parking lot topics

- **5:00 PM Transportation to Amgen Helix Facility**

- **6:00 PM – 7.30 PM Tour and reception, Amgen Helix Facility** (refreshments and hors d'oeuvres will be provided)
 - Return transportation provided, alternatively, additional dinner arrangements at your discretion

- **8:00 AM - 8:30 AM** Breakfast
- **8:30 AM – 10 AM** **Preparation for FDA teleconference**
 - Additional topics and questions All
 - Refinement of list Duncan Low, Amgen
- **10:00 AM – 10:15 AM** Break **10:15 AM – 12 Noon**
 - FDA Call in session with Ali Afnan and tbd
- **12 Noon - 1:00 PM** Lunch
- **1:30 PM - 3:00 PM** **Business case for PAT**
 - Benchmarking survey analysis Steve Doherty, Lilly
 - Business case Gert Thurau, Merck
 - Process transfer, contract manufacture Andrew Lange, Vertex
- **Meeting ends**
- **3:30 PM - 5:30 PM** **Optional tour of CPAC**

Improving pharmaceutical manufacturing

Voice of customer

Lean Six Sigma

Six sigma

VAVE, Kaizen

New technology

Robust design (Taguchi)



FMEA, DOE

Platforms

Quality Function Deployment
Program Management



Process Analytical Technology

Regulatory implementation

- FDA is currently engaged in agency-wide training
 - Initial program complete
 - Second program ongoing (CBER, CDER, CVM, ORA)
- EMEA formed an EU-PAT team
 - ‘very much in agreement with framework of FDA document’
 - Within ICH process for Q8 (Pharmaceutical Development) Q9 (Risk management) Q10 (Quality systems)
- Both active with external working groups
 - Consensus standards
 - Conferences/workshops
 - Academic programs
 - Professional societies

Regulatory status

- Voluntary
- Team approach for CMC review and cGMP inspection
- Several approvals (brand, generic, vetmed...)
- Several options for implementation
 - Existing products and processes (research data)
 - New products and processes
- Filing options
 - Within existing quality system
 - Supplement
 - Comparability protocol
- CONTACT THE PAT TEAMS!

Review and inspections

- Traditionally, innovations are introduced with new products and processes
- Existing products have a wealth of data from manufacturing as well as from development
- New technologies can tell us more about our products and processes, we shouldn't fear looking
- We make 'good' products, doesn't mean we can't make them better
- We can only arrive at the desired state through partnering and collaboration

The Macher Nickerson report

- Utilizes industry and FDA internal databases
- IT rules
- “The locus of decision rights impacts performance metrics”
- Use of CMO’s generally “correspond to inferior performance metrics”
- Use of PAT generally “corresponds to worse performance metrics”
- Scale and scope of the manufacturing facility have a complex interplay with manufacturing performance

Learning more - societies

PAT Community of Practice - Microsoft Internet Explorer provided by Amgen

Address: <http://www.ispe.org/PAT/default.htm>

Engineering Pharmaceutical Innovation

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ISPE PAT Community of Practice

Mission

Create a Global focal point of support and a d in PAT. This means the creation and delivery providing opportunities for collaboration and r

Purpose

The PAT Community of Practice will create an

- A network of active PAT practitioners from which promotes understanding, open comm about PAT and process understanding bet
- Training and opportunities, both formal an
- The development of appropriate case stu guidance
- A website which will act as a primary sou PAT and associated activities of value bot

Vision

We are the leading forum for PAT in the Pharr people in the industry. Members interact with career. They are our best advertising.

The inclusion of regulatory professionals is cr involvement and they see us as a key resour

Our community is global. We provide a comm

ASTM International Technical Committee E55 - Microsoft Internet Explorer provided by Amgen

Address: <http://www.astm.org/cgi-bin/SoftCart.exe/COMMIT/SCOPES/E55.htm?L+mystore+bgof7378+1145>

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Technical Committees

Technical Committees / Committee E55 / Scope

Committee E55 on Pharmaceutical Application of Process Analytical Technology

Staff Manager: [Pat Ficariello \(610\) 832-9720](#)

Committee Scope

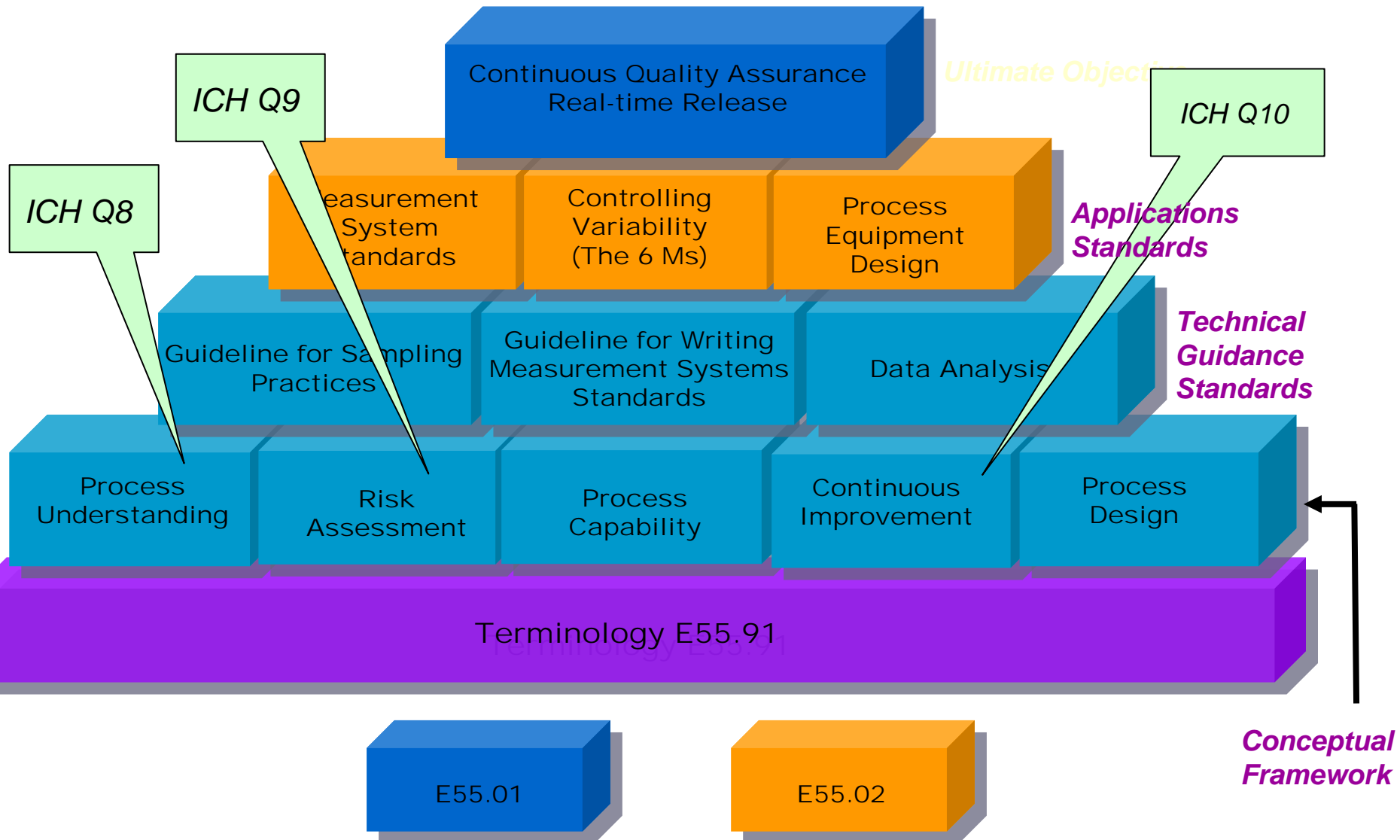
The scope of the Committee shall be development of standardized nomenclature and definitions of terms, recommended practices, guides, test methods, specifications, and performance standards for pharmaceutical application of process analytical technology. The Committee will encourage research in this field and sponsor symposia, workshops and publications to facilitate the development of such standards. The Committee will promote liaison with other ASTM Committees and other organizations with mutual interests.

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PAT Building Blocks

ASTM E55



Barriers to PAT implementation

- No patient shall go unsupplied!!
 - Take no chances with manufacturing processes
- Projects have to be driven across multiple functions
 - Cross functional teams, turf wars
 - Implementation takes 6-12 months
 - We have to take small, irreversible steps
- Management support is critical
 - Same for the FDA as it is for us

Conclusions - the PAT opportunity

- Securing product quality by process design rather than by 'after the fact' testing
- Developing dynamic processes which respond to variability by control of critical parameters
- Facilitating process changes in scale up and transfer through process understanding rather than extensive comparison
- Preparing for and enabling continuous improvement within a quality system with minimal regulatory barriers
- Excellence in design, excellence in quality and excellence in manufacture