- **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'ouevres will be provided)
  - Return transportation provided, alternatively, additional dinner arrangements at your discretion

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- **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

New technology

VA/VE, Kaizen

Robust design (Taguchi)

?

Program Management

Quality Function Deployment

Platforms

FMEA, DOE

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

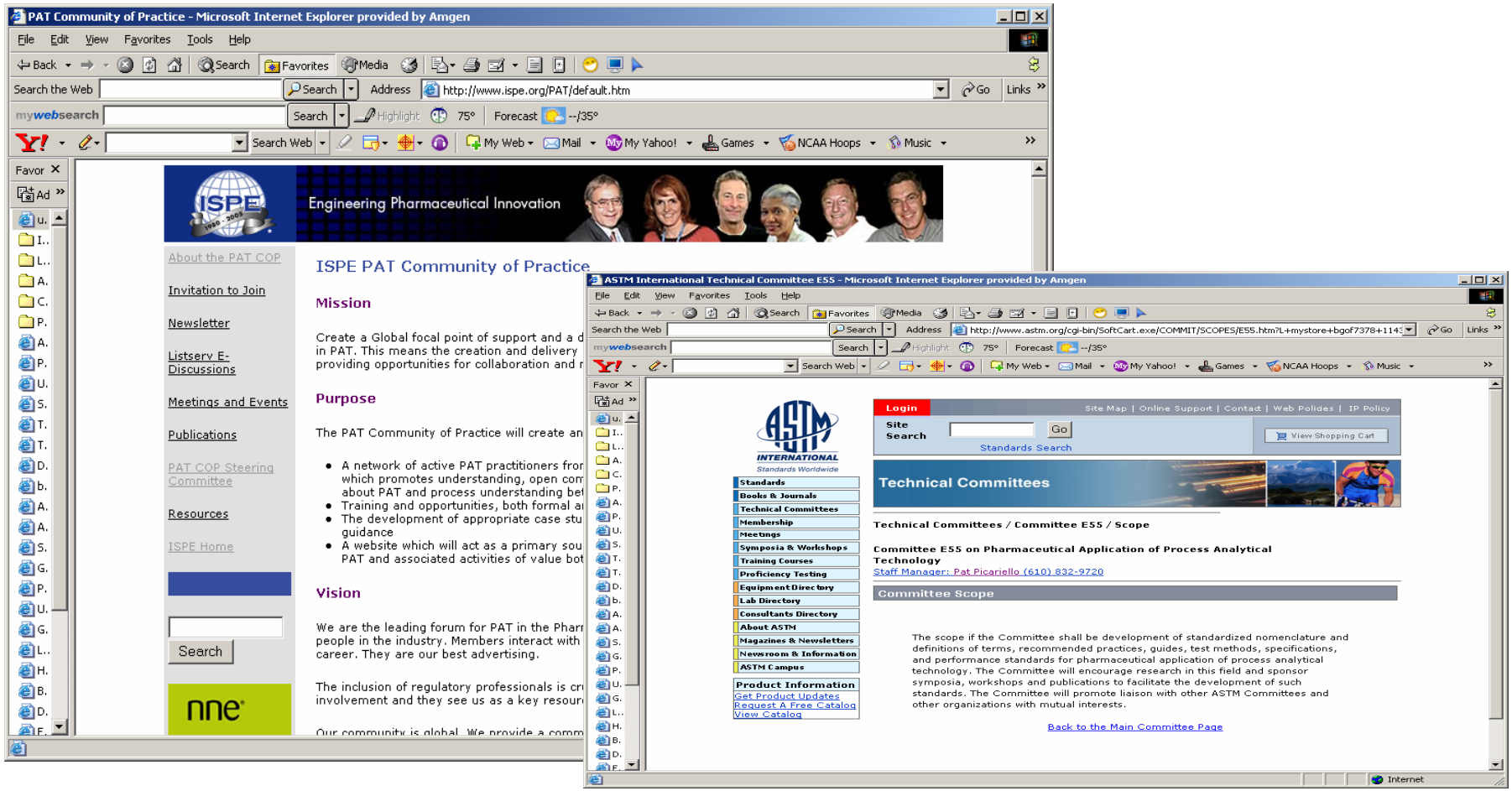
- Utilizes industry and FDA internal databases

- 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 - PAT meetings

17-Oct-06	18-Oct-06	Pharmaceutical manufacturing and Control	Reston, VA
23-Oct-06	25-Oct-06	PAT Implementation Strategies for Biotechnology	San Diego CA
24-Oct-06	26-Oct-06	PAT for Biologics	Dublin, IRE
5-Nov-06	8-Nov-06	ISPE Annual Meeting	Orlando, FL
21-Nov-06	22-Nov-06	Scientific Progress Underpinning PAT	Gothenburg, SV
28-Nov-05	30-Nov-05	ASTM E55 Pharmaceutical Application of PAT	Soeborg, DEN
28-Jan-07	31-Jan-07	IFPAC	
27-Mar-07	29-Mar-07	European Conference on Process technology	Nuremberg
1-May-07	1-May-07	Global PAT conference PDA	Washington, DC

Learning more - societies



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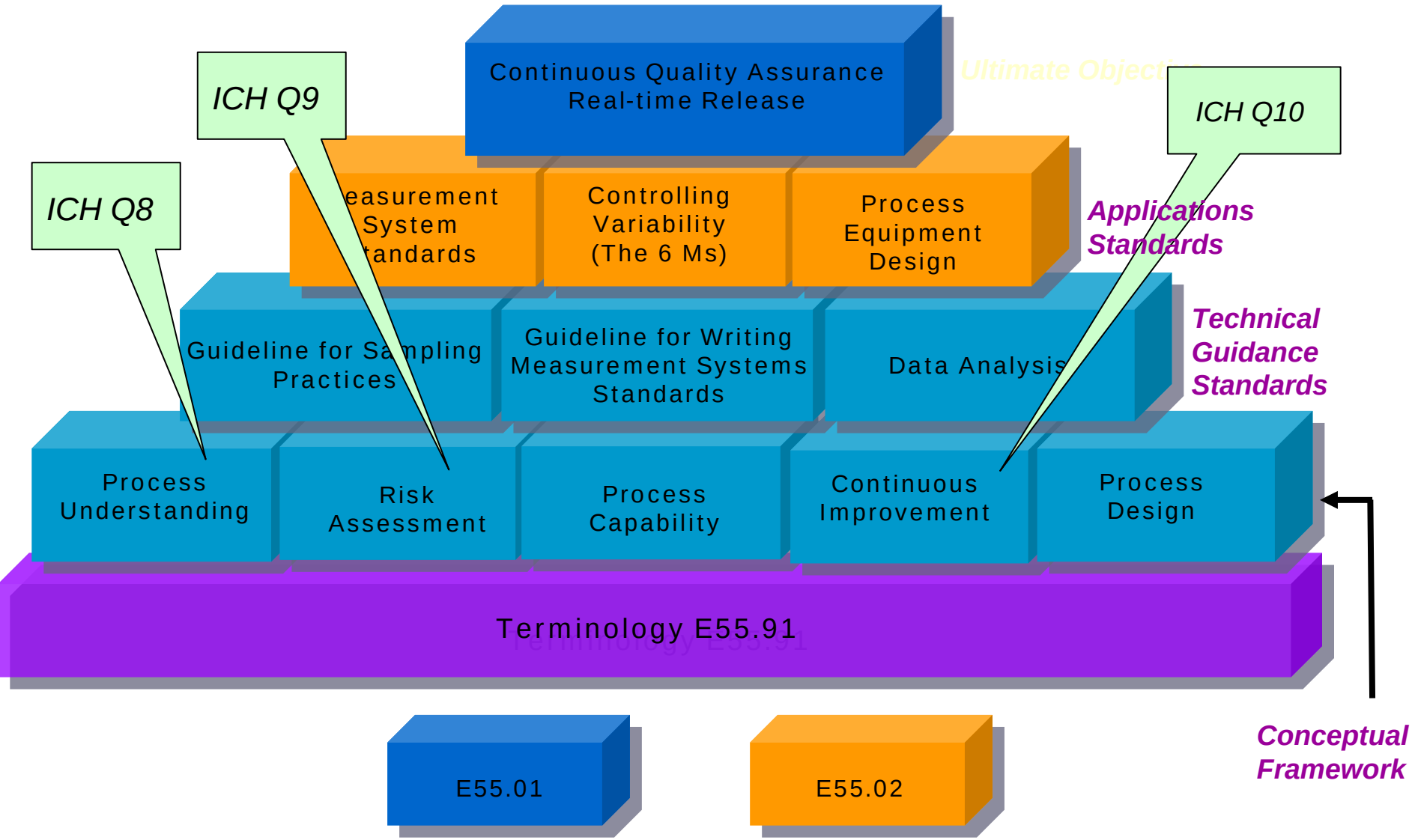
PAT Building Blocks ASTM E55



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