



2006 Schedule

Tuesday October 17th	
7:00 PM - 10:00 PM	<p>Informal Reception District Lounge, University Towers, Seattle (cash bar)</p> <hr/> <p style="text-align: center;">This provides an informal opportunity to relax and introduce themselves to the group or propose additional topics for discussion</p>
Wednesday, October 18	
7:30 AM - 8:00 AM	Breakfast (included)
8:00 AM - 8:10 AM	Introduction – Duncan Low, Amgen, Inc.
8:15 AM - 8:30 AM	Welcoming remarks – Jim Thomas, Vice President, Process & Analytical Sciences, Amgen Inc.
8:30 AM – 10:00 AM	<p>Status of PAT Today</p> <ul style="list-style-type: none"> • Regulatory Status – Duncan Low, Amgen • Developing standards and practices – David Radspinner, Thermo • International perspectives – Jan Gustafsson & Line Lundsberg-Nielsen, Novo Nordisk • Recent conference highlights – tbd
10:00 AM – 10:15 AM	Break
10:15 AM - 12 Noon	<p>Practical Approaches</p> <ul style="list-style-type: none"> • 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	<p>PAT and Quality by Design (QbD)</p> <ul style="list-style-type: none"> • 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 - 5:00 PM	<p>Benchmarking & preparation for FDA teleconference</p> <ul style="list-style-type: none"> • Introduction to benchmarking – Steve Doherty, Lilly • Gathering questions for the FDA – Duncan Low, Amgen • Parking lot topics
5:30 PM	Transportation to Amgen Helix Facility
6:00 PM – 8:00 PM	<p>Tour and reception, Amgen Helix Facility (refreshments and hors d'oeuvres will be provided)</p> <hr/> <p style="text-align: center;">Return transportation provided, alternatively, additional dinner arrangements at your discretion</p>



2006 Schedule

Thursday, October 19	
8:00 AM - 8:30 AM	Breakfast
8:30 AM - 10 AM	Preparation for FDA teleconference <ul style="list-style-type: none"> • Additional topics and questions – All • Refinement of list – Duncan Low, Amgen
10:00 AM - 10:15 AM	Break
10:15 AM - 12 Noon	<ul style="list-style-type: none"> • FDA Call in session with Ali Afnan and tbd <p style="text-align: center;">(moderator Duncan Low, Amgen)</p>
12 Noon - 1:00 PM	Lunch
1:30 PM - 3:00 PM	Business case for PAT <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Please notify Duncan Low (dlow@amgen.com) of your interest in this tour for planning purposes