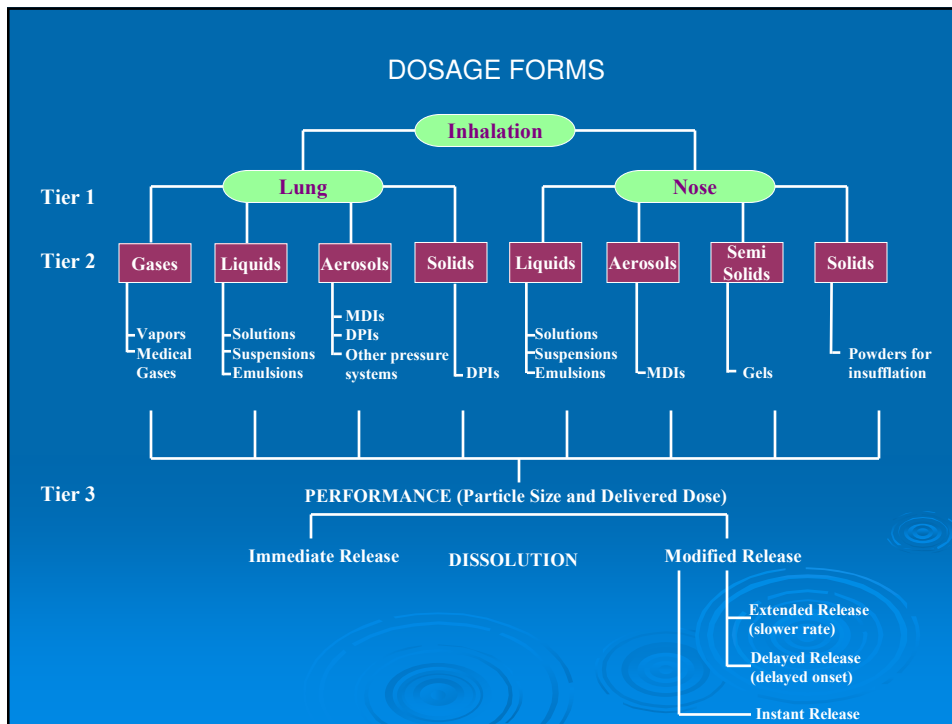


AIM in the Context of USP Actions

USP Activities

- Taxonomy
- General Chapters (2005-2010 cycle)
- Overview of Revisions to <601>
- Overview Inhalation Panel Workshop 2008
- Sequence of Events 2011
- Things that are likely to come up this year



General Chapters 2005-2010 Cycle

- To accommodate tier 2 (dosage form) and tier 3 (performance test) required:
 - preparation of General Chapter <5>
 - slight revision of existing General Chapter <601>
 - Possible addition of guidance chapter <1601>
- Roughly equivalent to 'Inhalanda' and 'APSD' chapters of EP.

Overview of Revisions to <601>

- Expanded section on mass balance
- Expanded section on leak testing
- New section on nasal product particle size determination describing laser diffraction method
- Restructured to include table of contents and clear subsections to make document navigable.

Workshop on Profile Comparisons and Discrimination of Particle Sizing Data USP, June 11th 2008

- Dave Christopher, Craig Dunbar, Charlie Thiel and Jolyon Mitchell speakers
- PQRI profile comparison working group program and conclusions outlined
- Limitations to current methods discussed
- AIM outlined
- Sufficient background given to prepare USP Pharmaceutical Dosage Forms committee (2010 – 2015 cycle) to consider AIM

Sequence of events 2011

- Spring - Publish GCs <5> and <601> in PF for public comment
- Summer - prepare recommendations for inclusion of AIM and data analysis in <601>
- Workshop to launch new GCs and outline future revisions with regard to AIM and data analysis – 12-13 December 2011 in Rockville, MD). Details at <http://www.usp.org/meetings/workshops/>.
- Publish a stimuli article on spacers

Questions

- High level
 - Implications for pharmacopoeial harmonization
 - Likely convergence of pharmacopoeial and regulatory standards
 - Role of specifications in application of AIM – change in philosophy at EP, reversal of trends in USP?
- Details
 - Fate of MMAD and GSD expressions as currently outlined in USP (note likely to be superseded by new approach)
 - Proposal for inclusion of full CI and transition to AIM (decision tree?)