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USP General Chapters and Their Impact on Industry:

GADA Perspective

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Commonalities to Generics & Pioneers

- Application of USP monographs
- Benefits of USP monographs
- Human vs. animal distinctions (including dosage forms, dissolution, etc.)
- Recent industry concerns
- Future topics of interest

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Characteristics of the Generics Industry

- Many generic companies are small; some are not well-funded
- Companies face certain competition in small markets
- Industry is not as well established as human generics
- There is a lack of involvement with USP & in monograph development

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Recent Industry Concerns: USP <467> Residual Solvents

- Lack of knowledge/involvement prior to implementation
  - Lack of industry involvement with USP
  - Effects on animal drugs considered?
  - Knowledge of change through human drug industry & CVM
- Confusion over requirements & CVM's application
  - Suppliers also unaware
  - CVM needed time to determine how to implement
  - Would CVM implement the same as CDER?

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Recent Industry Concerns: USP <467> Residual Solvents

- Supplier Issues
  - Education of suppliers
  - Lack of influence with suppliers: CofA modifications, providing methods
- Costs
  - Most generic companies are small with limited resources
  - Additional costs to outsource testing
  - Small markets; affects return on investment

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Lessons Learned

- Earlier knowledge/involvement in USP initiatives
- With CVM, industry must examine application to animal drugs
- CVM exemptions related to elemental impurities & subvisible particles showed appropriate consideration for animal drugs

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Additional Considerations of the Generics Industry

- How to address outdated monographs?
  - Test methods that do not work
  - Better methods exist or can be developed
- What are the benefits for industry to submit monographs or propose monograph changes?
- Industry sometimes confused about interface of USP and CVM requirements

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Summary

- Generic companies face many similar challenges as pioneer companies regarding USP monographs, but also can offer a varied perspective
- The generics industry identified lessons in the implementation of USP <467>
  - Industry and CVM must have more involvement, earlier, and must consider the effects on animal drugs and industry

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