

# Summary of Discussions

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IPAC-RS

PQRI Leachables and Extractables Workshop  
Bethesda, MD  
5 December 2005

# General

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- Requests to circulate the document more widely for review?
- Requests to provide posters and presentations electronically (CD or Web-site)

# Safety

- Clarify that between the SCT and the QT, structure activity data is sufficient, but that above the QT structure activity data plus other information (e.g., literature, further studies) is needed
- Clarify when in the qualification process genotoxicity studies are recommended (e.g., if there are no structural alerts, why need genotox studies if above QT; are SAR studies sufficient?)

# Safety (2)

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- Consider clarifying application of thresholds to products with short term duration of exposure
- Consider removing structural alert compounds from QT database?
- Consider discussions with USP to look at <87>, <88>, <381> and <661> for revision in context of OINDP

# Chemistry

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- Importance of relationship with supplier(s)
  - IPAC-RS supplier QC guidelines
  - Can contact Barbara Falco (Kos) or Melinda Munos ([mmunos@gcd.com](mailto:mmunos@gcd.com)) for more info

# Chemistry

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- Consider if need to clarify recommendations for ancillary components
- Consider greater emphasis on discussion of volatiles (head-space evaluation) in extraction studies
- Discuss potential for parallel extractables and leachables studies

# Chemistry

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- Consider specific clarifications on calculation and use of AET based on questions today

# Comments

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- Feel free to send any further comments to the Working Group
- Can submit written comments to us today (sheet in binder)