

Opening Remarks – Day 2

**PQRI Workshop on
Leachables and Extractables
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Highlights

Day 1

- **Threshold Principles**
 - TTC is a risk assessment tool based on the principle of establishing a human exposure threshold value for all chemicals , below which there is a very low probability of an appreciable risk to human health
- **SCT**
 - 0.15 µg/day
- **QT**
 - 5 µg/day
- **AET**
 - Corresponds to the SCT

Highlights

Day 1

- Quality by Design
 - Early Assessment
 - Pharmaceutical Team
 - Chemist
 - Toxicologist
 - Supplier
 - Lessoned Learned

Specifics of Best Practices Recommendations

- Component Selection
- Controlled Extraction Studies
- Leachable Studies and Routine Extractable Testing
- Development and Application of the Analytical Evaluation Threshold

Science, Process, and Perspectives

- Summary and Discussion of Safety and Best Practices
- Review of Sessions
- FDA Perspective
 - Regulatory Science Strategies
 - Safety Recommendations
 - Open Discussion
 - Direction for Leachables/Extractables