

PQRI Workshop on Leachables and Extractables: Specifics of Safety Recommendations



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Office of New Drugs

Center for Drug Evaluation and Research

Food and Drug Administration

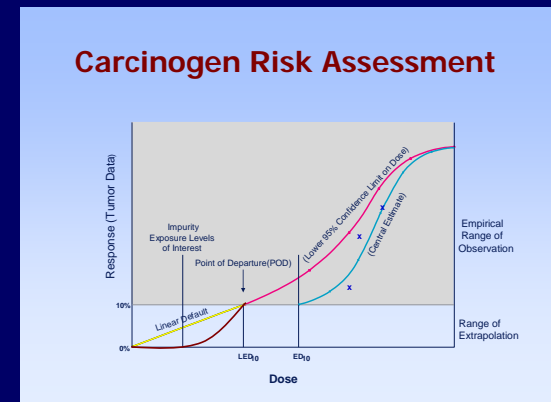


Food and Drug Administration



The “science” of risk assessment

- **Otto von Bismarck:** “Laws are like sausages, it is better not to see them being made.” To this I would add risk assessments.





Kudos to the workgroup for producing an outstanding document

SAFETY THRESHOLDS AND BEST PRACTICES FOR EXTRACTABLES AND LEACHABLES IN ORALLY INHALED AND NASAL DRUG PRODUCTS

Submitted to the PQRI DPTC
by the
PQRI Leachables and Extractables Working Group

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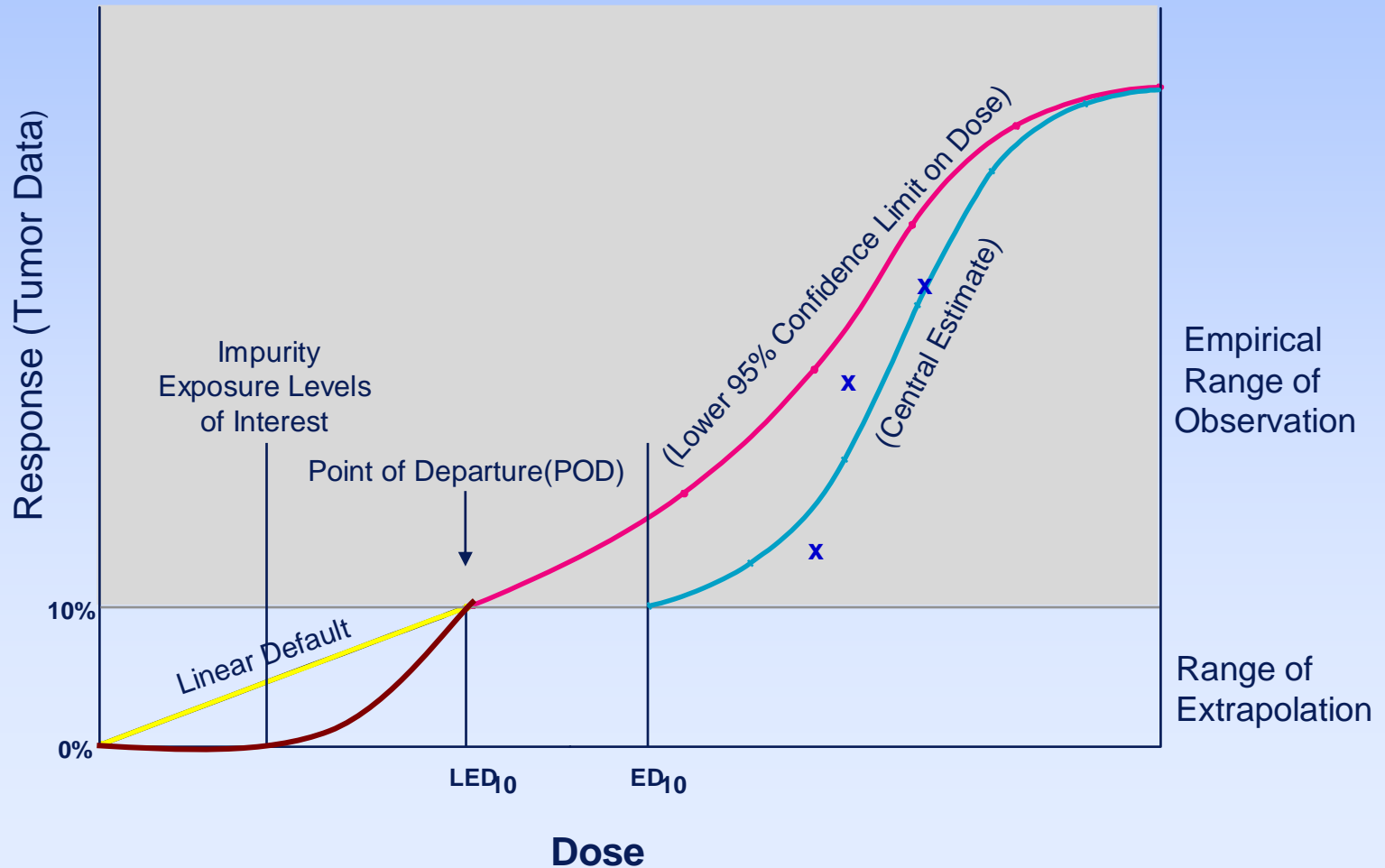
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Carcinogen Risk Assessment



Utility of “Safety Concern Threshold”

- Values are science based
- Risk assessments are conservative with a number of “safety factors” built in
- Allows for the qualification of contaminants without laboratory experimentation; conserves resources and use of animals
- Public health is protected



Presentations this afternoon

- **Development and Justification of Safety Concern Threshold**
 - ◆ **Mark Vogel, Ph.D., Pfizer**
- **Development and Justification of Qualification Threshold**
 - ◆ **Ron Wolff, Ph.D. Nektar Therapeutics**
- **Safety Qualification Process and Application of Thresholds**
 - ◆ **Jim Blanchard, PhD. Aradigm**

