Physiologically Based Pharmacokinetic (PBPK) Modeling to support dosing recommendations for patients with renal Impairment– Are we there yet?

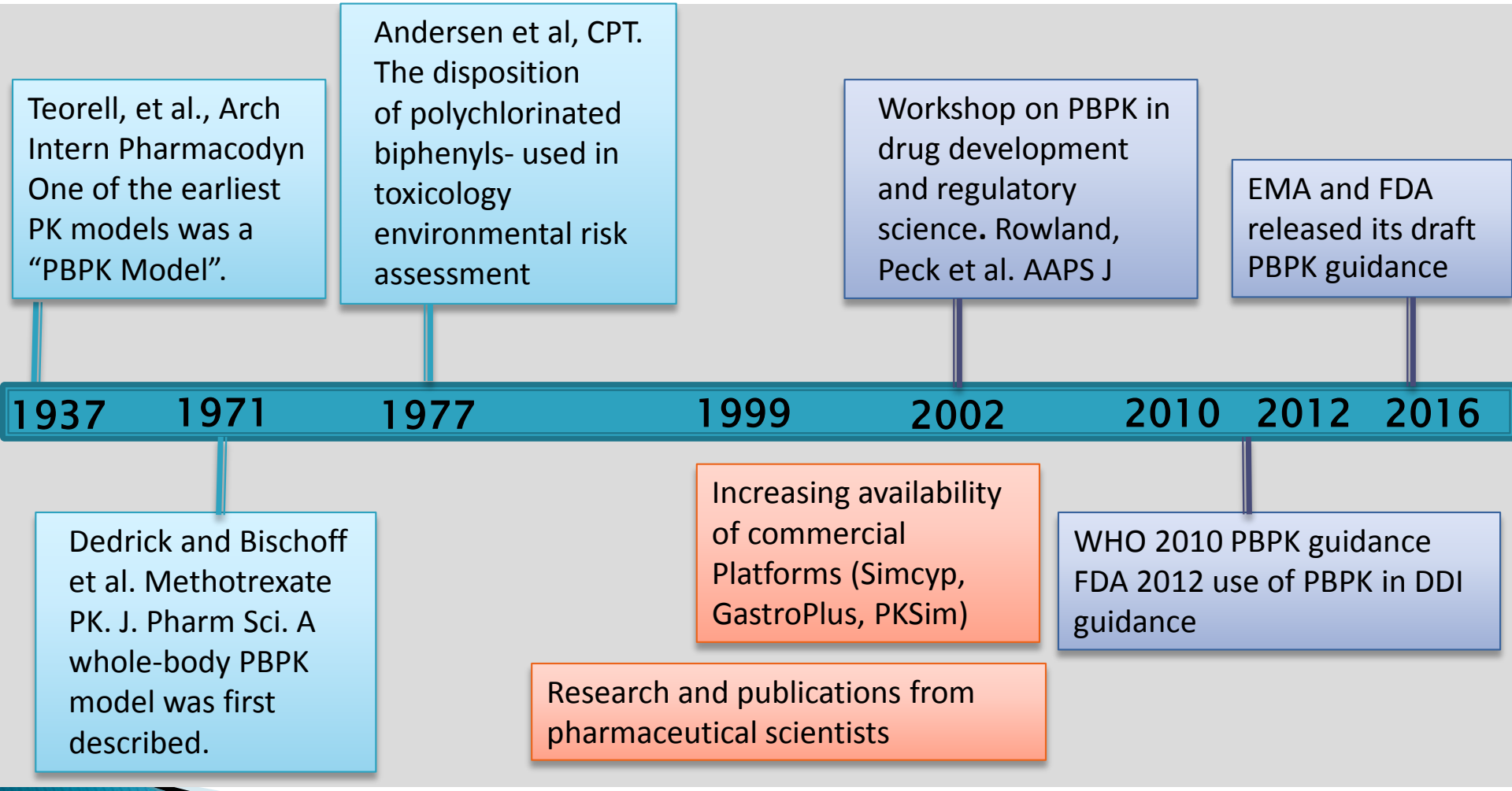
2017 ASCPT Workshop

Friday March 17 1:15-2:45 PM

Chairs: Ying Ou, Amgen & Robin O'Connor-Semmes, PAREXEL

Network and Community: Development, Regulatory and &Outcome (DRO), Regulatory Science; Quantitative Pharmacology (QP), Pharmacometrics & Pharmacokinetics

A Brief History of PBPK Models



CPT: Clin Pharmacol Ther

Objective of Workshop

- **To provide an update on the current state of a timely topic - potential use of PBPK for dosing recommendation for patients with renal impairment.**
  - There have been multiple examples of drug labeling for drug-drug interaction (DDI) informed by PBPK, however the use of PBPK to support drug labeling for renal impairment dose recommendation is limited.
  - Dedicated renal impairment studies can be challenging to conduct due to patient access difficulties (e.g., patients with severe renal impairment and ESRD patients not on dialysis).

Workshop Agenda

- **Introduction:**
  - Objective of workshop and a brief PBPK history
- **Speaker 1: Dr. Steve Hall: PBPK Modeling to support dosing recommendations for patients with renal Impairment–Effects on non-renal clearance**
- **Speaker 2: Dr. Ping Zhao: The readiness and specific paths of using PBPK support dosing recommendation in patients with renal impairment**
- **Speaker 3: Dr. Kathy Giacomini: Towards quantitative prediction of the effect of renal impairment: filling the gap for drug transporters**
- **Each speaker will have ~ 25 minutes (including Q&A) for the presentation**
- **Additional Q&A session (5 to 10 minutes) toward the end of the workshop**