A *NIPTE* PROPOSAL

"NEW" PRIOR KNOWLEDGE for Generic Product Development

Problems: 1) too many review cycles, 2) many under represented complex products, 3) out of date characterization of older products

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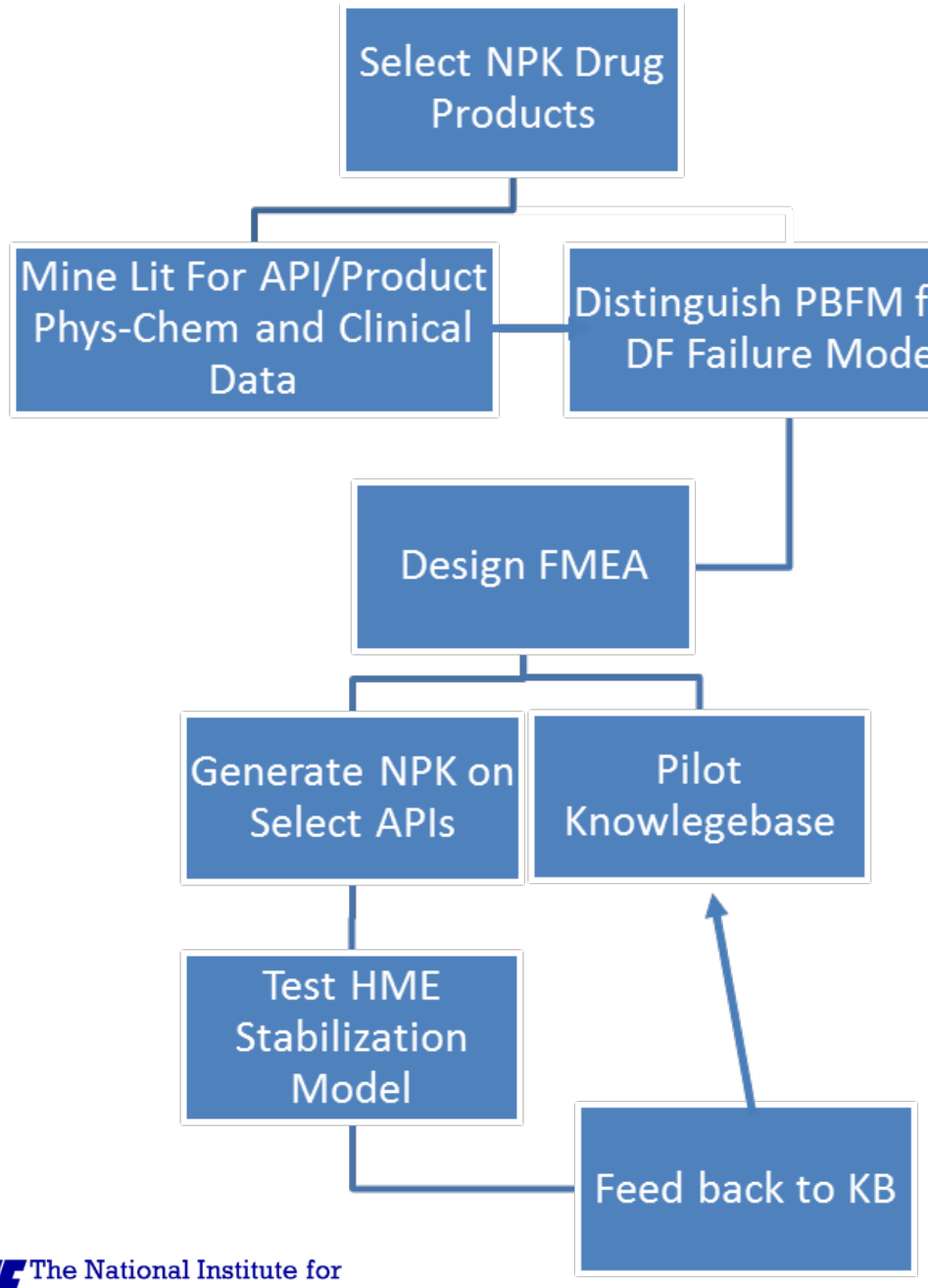
A **NIPTE** based effort to identify the next tranche of compounds/products likely to be important targets for the generic industry. A systematic application of risk-based scientific methodology will be used to design experiments and produce the critical data for selected compounds to generate the ***"new" prior knowledge"*** to direct formulation and process design strategies.

- **First**, drug products coming off patent within the next 0-5 years will be identified and prioritized according to the complexities associated with generic uptake.
- **Second**, specific issues associated with API form, formulation, control strategies, and processing complexities will be highlighted and communicated so as to ensure on-time approval – providing value for public health and cost to society.



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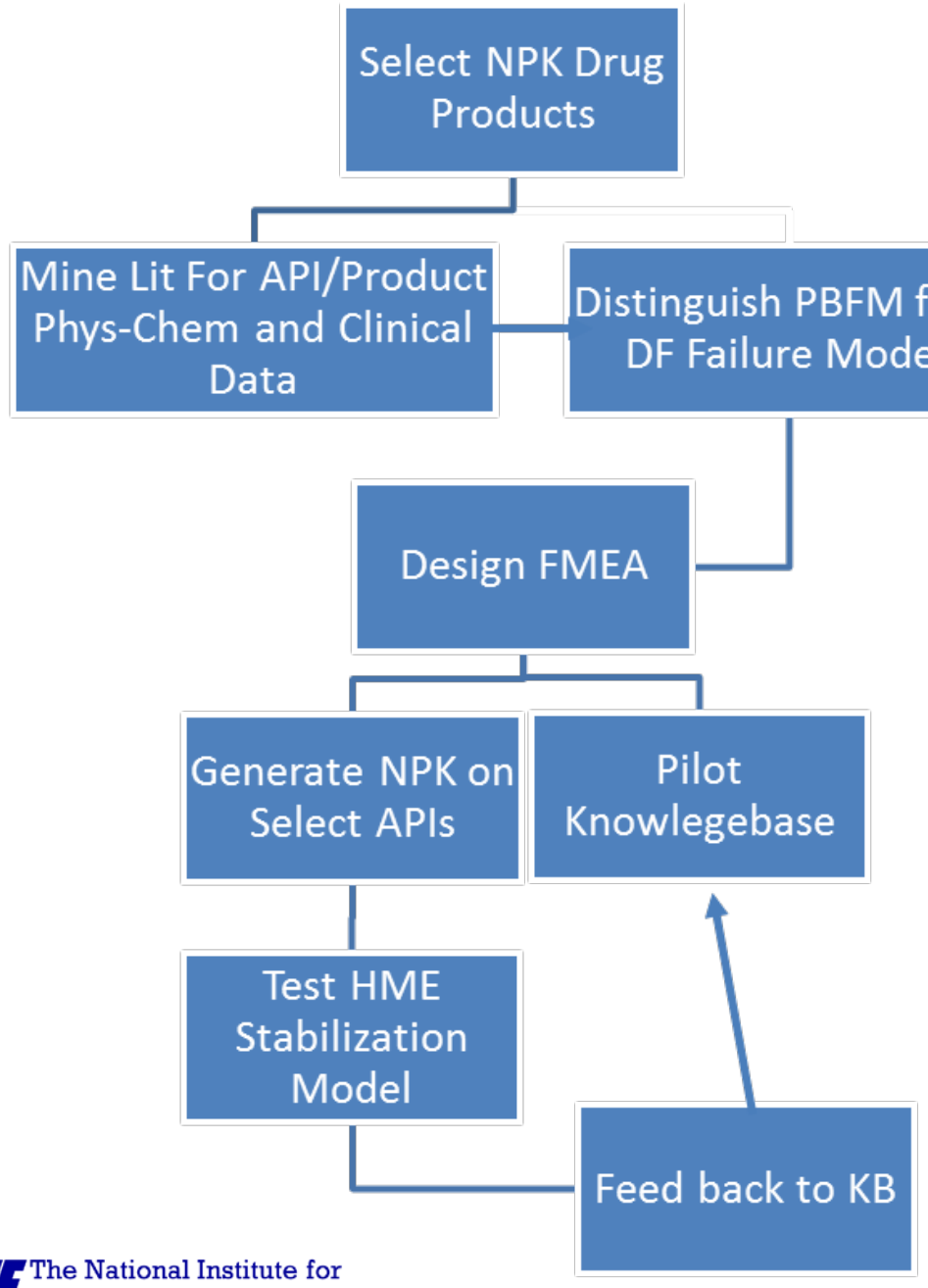
- **Third**, failure modes will be evaluated and manufacturing/formulation complexities distinguished from patient compliance problems.
- **Fourth**, failure mode and effects analysis (FMEA) for formulation and process design will be performed enabling a detailed risk assessment. Pilot studies will be conducted and ***"new prior knowledge"*** will be generated and made available for public consumption.
- **Fifth**, a public knowledgebase will be developed and rolled out. The excipient database, prepared previously by **NIPTE,** will serve as a model database.



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