IPEC-Americas Recommendations for Increasing Collaboration and Transparency with Drug Ingredient Suppliers

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Multiple stakeholders; **one objective.**

International Pharmaceutical Excipients Council

Collaborative solutions for excipient industry stakeholders

Importance of Excipients in Generic Drugs

- There is an increased understanding of the **importance of excipients to the quality and substitutability of generic drugs.**

- IPEC-Americas would like to make the following two requests targeted at increasing FDA collaboration and transparency with all drug ingredient suppliers:

Request #1

- **IPEC-Americas would like to recommend that the FDA collaborate more directly with members of the excipient industry** to ensure improved transparency in selecting the specific studies to support and in interpreting or implementing results from the studies.
  - Subject Matter Experts can contribute valuable knowledge and experience to **help FDA better select and design projects to achieve their objectives**.
  - These experts would also be instrumental in **assisting with the review and interpretation of the results.**
  - Most excipients are produced by chemical companies whose primary focus is not in supplying to the pharmaceutical industry.
  - R&D resources in the chemical industry allocated to fundamental research have been significantly reduced in the last decade.
  - ***Therefore, if the FDA is expecting a more fundamental understanding of excipients, then perhaps the FDA Regulatory Science initiative program will need to help fund fundamental studies/research in this area.***

Request #2

Background

Recently IPEC-Americas and the IQ Consortium met with members of the FDA for a **Critical Path Innovation Meeting**.

During the meeting, industry proposed a critical path initiative for a **"novel excipient qualification process"** which was modeled after the "Biomarker qualification process."

- **IPEC-Americas believes there should be a <u>follow-up meeting with the FDA related to generic drugs</u>**
  - **Expand** the CPI qualification process under development for novel "new chemical entity" excipients to **include other types of novel excipients which are used in generic drugs** (such as **co-processed excipients, new grades of existing excipients within a family, higher use levels than what is listed in the IID and/or modified routes of delivery**).

Thank You!