SUPAC Equipment Addendum
Eight Years in Use Eight Years Strong

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Introduction

Eight years ago ISPE in cooperation with FDA rolled out what has become to be regarded as the most significant guidance for industry in many years. The "Guideline for Industry: Manufacturing Equipment Addendum for SUPAC", guidance was a major breakthrough as far as FDA regulation is concerned. The partnership with FDA was strong and the shared vision with ISPE brought this landmark guidance into every day use. The subsequent cost savings to industry is incalculable. But the most laudable aspect of the equipment addendum is its staying power as it is still routinely referenced eight years later.

History and Our Mission

At FDA's invitation, ISPE collaborated with the Office for Regulatory Affairs (ORA) and the Center for Drug Evaluation and Research (CDER) to develop a list of "similar equipment." The list was needed for the implementation of CDER's Scale-Up and Post Approval Changes (SUPAC). Each SUPAC guide would cover a selected dosage form. The guides envisioned included immediate release solid dosage forms, modified release solid dosage forms and semi-solid topical dosage forms. Each guide required an associated equipment addendum.

SUPAC defines manufacturing changes, directs how CDER is notified and specifies the data to accompany change submissions. The "similar equipment list" or equipment addendum (EA) classifies comparable equipment by design and operating principle. The implementation of SUPAC with the associated equipment addenda has simplified CDER review of submissions. This simplification has proven to provide a significant cost saving effect for industry stakeholders.

FDA came to ISPE because it represented a worldwide network of 10,000 engineers with broad based experience with manufacturing equipment. FDA and ISPE have an excellent relationship having crafted together and delivering on several key tasks. An example of which is the Baseline guides for industry.

Many things have changed since that time including issuance of the “Changes to Approved NDA and ANDA”, Industry Guidance in 1999. The utility of the equipment addendum, however, continues to be valid with its’ main purpose of describing same design and operating principles for pharmaceutical processing equipment.

Chronologically these documents from conception to ultimate acceptance by FDA and roll out to industry may be summarized:

- SUPAC EA Immediate Release (IR) Team Formed 10/96
- SUPAC EA Immediate Release (IR) Guidance issued 10/97
- SUPAC EA Modified Release (MR) completed 11/97
- SUPAC EA IR and MR documents merged 11/97
- SUPAC EA IR/MR Guidance issued 4/98
- SUPAC EA Team and FDA Meeting 6/98 for Final Roll Out
    - Introduction section updated for industry
    - Formal change control established to:
        - Maintain equipment list current
        - Track technology changes
        - Assure list undergoes expert peer review periodically
    - Set up training for industry and FDA end users
- SUPAC EA Semi-Solid completed 6/98

EA = Equipment Addendum

The SUPAC equipment addendum committee created a mission statement which embraced these efforts as well as providing for the mandatory maintenance of the EA which was foreseen.

“To encourage free and open communication with regard to the use, design and operating principles for Pharmaceutical Processing Equipment within the Pharmaceutical Industry; to assure clarity and uniformity when dealing with process descriptions and regulatory changes; to make these data available to the industry by fulfilling the role of clearing house as well as providing expert peer review when documenting equipment classifications while maintaining the custodial duties of equipment comparability documentation.”

Recognition

The genesis of the equipment addendum documents covers the selfless efforts of over 60 ISPE professionals including engineers, pharmaceutical technologists and ISPE staff.

For these efforts at that time Vice President Gore's Committee for National Performance Review (NPR) presented the Vice President's *Hammer Award* to FDA's Office of Regulatory Affairs, Center for Drug Evaluation and Research and ISPE. The Hammer Award is given to federal employees and their partners who advance the NPR's goals of cutting red tape, improving customer service and building a better and more cost effective government.

References:

"FDA's SUPAC Guidances: What Are They and How Do They Help?" R.Poska , August 1998

S.Stringer, "Pharmaceutical Engineering," 18, 1, p.46 Jan/Feb 1998

P.Jones, "Pharmaceutical Engineering," 17, 2, p.38 March/April 1997

"Workshop on SUPAC Equipment Addendum," ISPE Annual Meeting Nov. 1998, R.Poska, R.Somma