

Call for comment and information on the draft mock P2

June, 2008

Within the Health Science Study on “Effective Pharmaceutical Development and Pharmaceutical Assessment”(H18-Iyaku-Ippann-003), the Enhanced Approach subgroup on “Design Space Development for Critical Manufacturing Steps and Real Time Release as a Control Strategy” (attachment file A in Japanese) prepared a draft P2 mock(attachment file B in Japanese or file C in English). The group would like to receive comments and information regarding the draft mock. Should you decided to send comments and or information, please follow the instructions below. We plan to use the comments and information for future activities of the research group.

We, however, cannot respond to comment individually.

Instructions

1. Deadline for submission: September 3, 2008.
2. Send your comments and information using the attached format (file D) to the e mail address below. Postal mail, FAX or telephone call will not be received.
E mail address q8_g1pubc@nihs.go.jp
3. Please identify yourself and your organization with address if any.
Contents of your comments may be disclosed for reporting purposes. But your identity will NOT be published.

Sincerely,

Yukio Hiyama
Lead of the enhanced approach subgroup
National Institute of Health Sciences