EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
General Recommendation – ESTRI Gateway

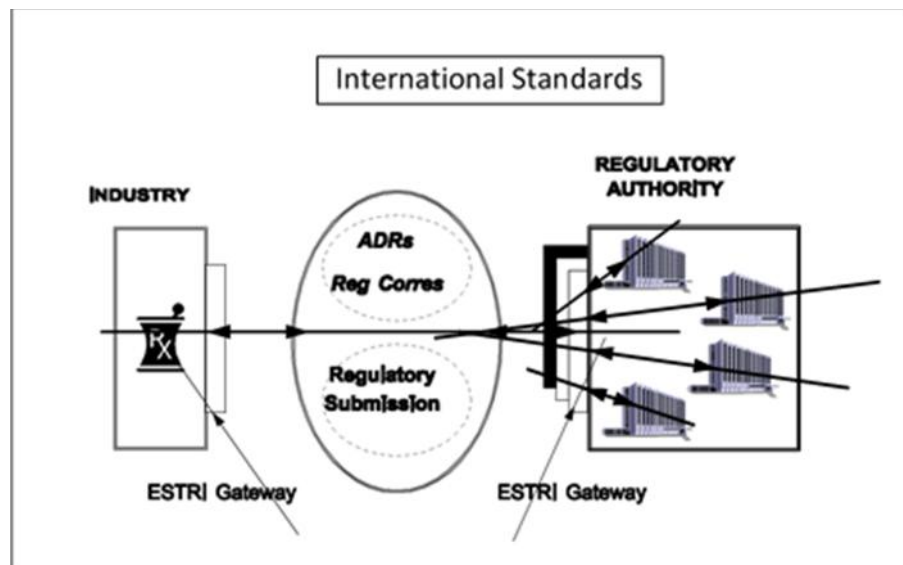Version 3.0 - 11JUN2015

Title: ESTRI Gateway

Background: Electronic exchange of regulatory information offers the potential for significant time and resource savings for both Industry and Regulatory Authorities. Internationally accepted standards for both the content and transport of regulatory information minimizes many of the obstacles preventing the achievement of this objective.

Standards covering the transport, format, and security of information are within the remit of the M2 Expert Working Group while content definition is the responsibility of other ICH EWGs. Due to the rapidly changing nature of technology, it is anticipated that the standards will continue to evolve. To accommodate change, the M2 EWG maintains a core set of recommendations which represent the current complement of approved standards that support the ICH regions.

ESTRI Gateway: The M2 EWG considered a number of alternatives and concluded that an appropriately configured gateway provides the only viable solution for the electronic transfer of regulatory information at this time. This gateway concept for communication between parties exchanging information is essential to the success of this effort.

As illustrated in Figure 1, this concept (referred to as the ESTRI Gateway) enables Regulatory Authorities and Industry to electronically exchange and share regulatory information. Based on the ICH recommended standards, all communication partners can extract information from internal databases, create the regulatory communication, and send to the receiver with confidence that it will be received intact and protected, regardless of the technology of their internal systems.

Figure 1: Representation of the ESTRI Gateway

The ESTRI Gateway is a data exchange portal that supports regulatory communication based upon a set of standards.

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Definition: An ESTRI Gateway concept is compliant with the ICH-recommended standards. Regulatory Authorities and Industry will implement the set of standards and will be able to transmit to and receive information from all other parties who have implemented such an ESTRI Gateway, regardless of their technical infrastructure.

The ESTRI Gateway concept will be based on individual standards addressing different aspects of the regulatory communication. The following is a list of areas that are currently being addressed by the M2 EWG. Other standards areas will be addressed by the M2 EWG in developing a total solution for regulatory communication.

- File Format (e.g., PDF/A)
- File Integrity (e.g., SHA-256)
- Information Transfer (e.g., EDIINT)

It is the intention of the M2 EWG to keep the number of recommendations to a minimum, i.e. a single standard should be recommended where possible.

The on-going identification and recommendation of standards will allow an ESTRI Gateway to be implemented and to evolve in a systematic manner to accommodate other aspects of regulatory communication through a single point of implementation and maintenance.

Recommendation:

The M2 EWG recommends the ESTRI Gateway concept with the following definition:

- In each ICH Region the Regulatory Authorities will implement at least one ESTRI Gateway for communication with Industry and with other Authorities that consists of a set of core standards and functionality required to support the standards. In those instances where multiple standards are recommended for a specific use case, the Regulatory Authority will implement at least one of these standards. Where possible, the Regulatory Authority will implement all recommended standards and will endeavor to maintain compatibility with other ICH regions.

Conditions:

- This approach will accommodate instances in which a Regulatory Authority may choose to support a specific language implementation of a standard (e.g., Japanese and English) if their regulations require submission in that language.
- Industry and Authorities may use any mutually agreeable mechanism for electronic communication in the case of information categories for which standards have not yet been adopted.

Remarks:

- There may be instances in which Industry and Regulatory Authorities agree that it is mutually advantageous to use an approach for a particular regulatory communication which differs from the Core Standard Set.
- It is expected that the Regulatory Authorities will share information about technologies being used and those being considered.