



IP COP Clinical Supply Information Systems Task Team Member Position Description

Updated 08-Mar-12

IP COP Clinical Supply Information Systems Task Team Overview:

The ISPE Investigational Products Community of Practice is sponsoring an effort to develop a Good Practice Guide for Clinical Supply Information Systems. Members from pharmaceutical and biotechnology companies and contract service providers are invited to participate on the task team.

Rationale: Currently there is no industry guideline or standards for clinical supply information systems. Systems to manage and control investigational products have commonality but also have some very unique requirements as compared to systems that manage commercial products. The current lack of standards for supply information systems can often make efficient information sharing, data exchange and controls between internal and external systems difficult. These challenges are due largely due to differences in nomenclature, approaches in organizing and managing data, as well as business rules, and quality and regulatory controls across the current custom and COTs systems in use today.

Position Purpose and Objectives:

The primary objectives of the task team will be to develop a guideline that will assist companies when:

- Evaluating the purchase of a Commercial Off-The-Shelf (COTS) System
- Designing a custom system or customizing a COTS system
- Interfacing with other systems

The guideline will cover key business requirements and controls; key data elements (e.g., terminology, relationships, standards, messaging schema); and technical considerations

Appointed by: Task Team Lead

Responsibilities of this Position:

- Attend and actively participate in biweekly 1 hour Task Team meetings (teleconference)
- One representative from each company on team (can involve others ad hoc to review and contribute to guideline)
- Writing, reviewing and getting internal comments in between meetings

Skills/Experience Requirements for this Position:

- The incumbent should be an ISPE member
- The incumbent should be a subject matter expert in the discipline of the COP (Investigational Products)
- The incumbent must have strong leadership skills
- Project management skills are a plus

Length of Service: 12-18 months until Guidance Document is published

Time Commitment: Approximate hours per month: >0 to 5 Hours

Work will be intermittent regular regular with peaks requiring additional effort.

Resource Requirements

Provided by ISPE staff or volunteers: The Task Team Chair will provide guidance on the assignments of the Task Team members. The Guidance Document Executive Committee and the IP COP Council will provide guidance on the assignments of the Task Team as a whole.

Expected from the volunteer (or his/her employer): Active participation is expected from all Subcommittee members. Subcommittee members should have commitment from his/her employer to allow participation in committee meetings during working hours. Access to electronic tools (email, internet) is expected.

Meeting Schedule:

Task Team meetings are 1 hour teleconferences held on a bi-weekly basis. Work will start May 2012 and continue until mid or late 2013.

Attendance Requirement:

Task Team Members should attend a minimum of 75% of the meetings; all of them if possible.

Volunteer Expectations

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| <ul style="list-style-type: none"> ✓ <i>Actively participate in meetings</i> ✓ <i>Read materials and come prepared to each meeting</i> ✓ <i>Listen to people and ideas</i> ✓ <i>Become knowledgeable of the Society's policies and procedures</i> ✓ <i>Complete assignments on time</i> | <ul style="list-style-type: none"> ✓ <i>Respond to communications in a timely manner</i> ✓ <i>Develop a good relationship with Staff</i> ✓ <i>Respect confidentiality</i> ✓ <i>Fully support all decisions of the Board and Committee</i> ✓ <i>Always act in the best interests of ISPE</i> |
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If you are interested in volunteering for this position please click the link to complete a Volunteer Profile

<http://www.ispe.org/volunteerprofile>