

ENGINEERING PHARMACEUTICAL INNOVATION



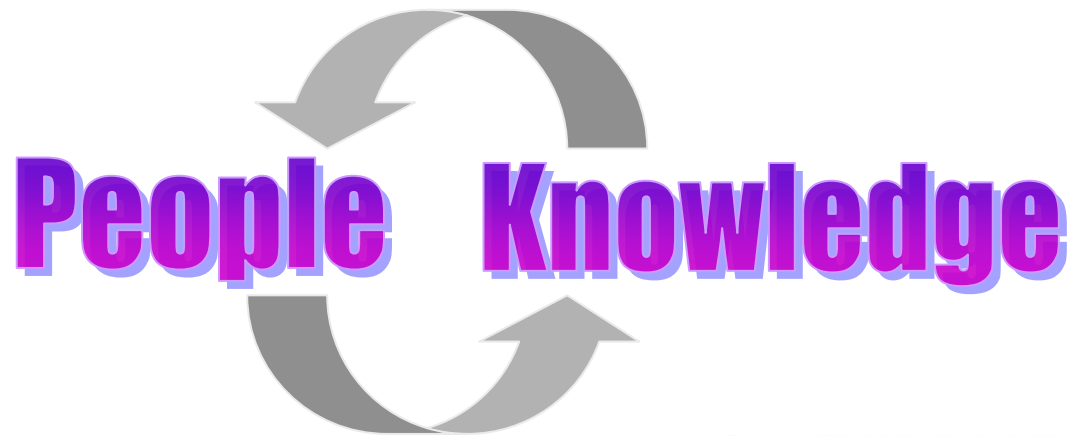
ISPE COMMUNITIES OF PRACTICE (COPs)

Dr Jan Gustafsson,
COP Council & PAT COP,
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What is a COP for? (elevator definition)

Connecting & Collecting

- Connecting members person-to-person
- Collecting relevant information to share



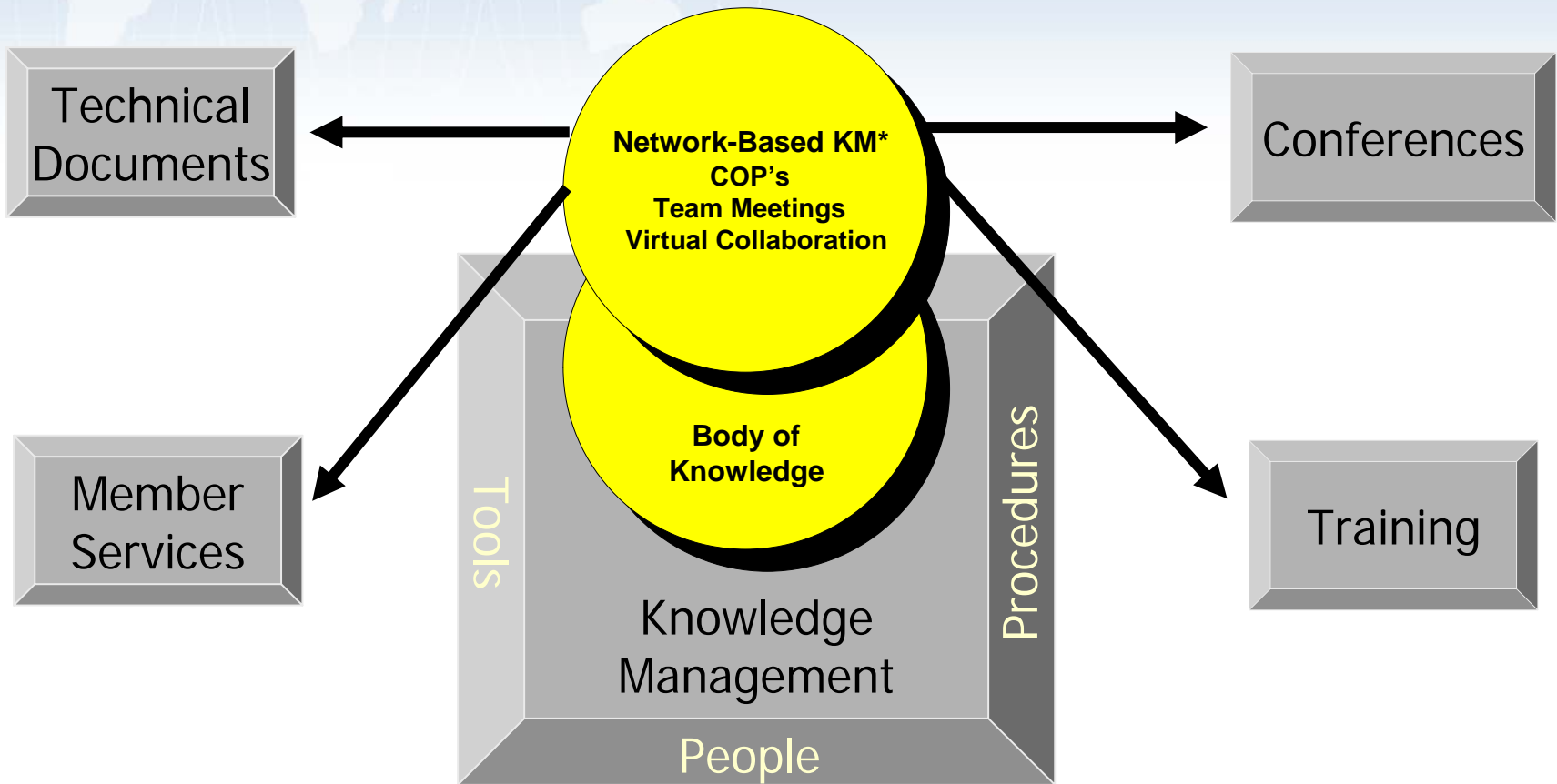
ISPE COMMUNITIES OF PRACTICE

- ISPE Communities of Practice (COPs) offer pharmaceutical manufacturing professionals a dynamic **forum** to gain **relevant and timely information** through **discussions and networking opportunities**.

What is a COP for? (ISPE definition)

- To provide a forum for community members to help each other solve everyday work problems and engage in active networking
- To develop and disseminate best practices, guidelines, and procedures for use by community members
- To organize, manage, and research a body of knowledge from which Community members can draw
- Innovate and create breakthrough ideas, knowledge, and practices

LINKS between COPs and other ISPE Activities



EXISTING ISPE COMMUNITIES OF PRACTICE

- Active Pharmaceutical Ingredients (API COP)
- Biotech (BioCOP)
- Clinical Materials (CM COP)
- Commissioning and Qualification (C&Q COP)
- Containment (Containment COP)
- Critical Utilities (CU COP)
- HVAC (HVAC COP)
- Investigational Medicinal Products (IMP COP)
- Good Automated Manufacturing Practice (GAMP COP)
- **Process Analytical Technology (PAT COP)**
- Process/Product Development
- Project Management (PM COP)
- Sterile Products Processing (SPP COP)

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ISPE PAT Community of Practice

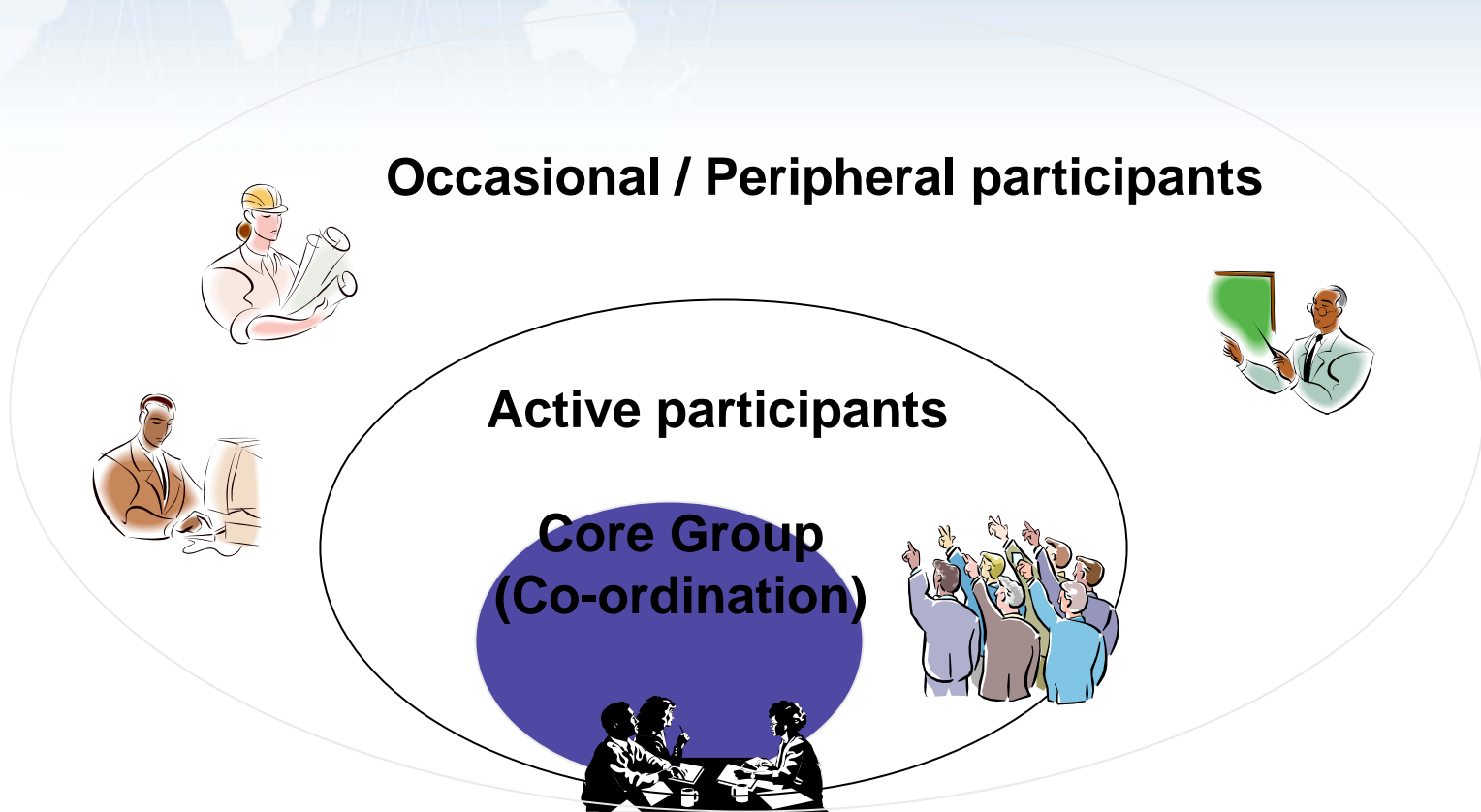
Value to Community Members

- Opportunity to **exchange knowledge and experience** with other like-minded professionals through convenient global networking forums
- **Provide tools** to enhance productivity and keep current on industry trends and developments
- Enhance your **professional reputation**

Value to Organizations

- Availability of a community-specific **Body of Knowledge** by subject matter experts
- Ability to positively **influence the pharmaceutical manufacturing profession**
- Generate **new knowledge** in response to problems and opportunities
- Promote **common language and terminology**

Types of Participation



A community is a living entity ... not unlike a family

Steering Committee



One International Team

- Carl Anderson (Duquesne University)
- Nissan Cohen (Start-Up Business Development)
- Ian Flawn-Opana (Ferring Pharmaceutical A/S)
- Rick Godec (GE Analytical Instruments)
- Jan Gustafsson (Novo Nordisk)
- John Hannon (Commissioning Agents)
- Greg Harris (Alcon Lab)
- Connie Heinze (Nordic)
- Munetaka Hattori (Japan)
- Eric Johnston (Watson Pharma)
- John Levins (Wyeth)
- Duncan Low (Amgen)
- Line Lundsberg-Neilsen (UK)
- Gawayne Mahboubian-Jones (Optimal Ltd)
- Erin McCaffery (FDA CDR)
- Joe Phillips (ISPE)
- David Selby (Selby Hope Intl)
- Joep Timmermans (Pfizer)
- Eric Unrau (CRB Consulting Engineers)
- Kevin Wall (Jansen Pharma)
- Christian Woelbeling (Werum, Germany)



PAT Objectives

To easily connect ISPE members to:

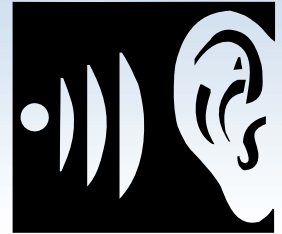
- people with a shared interest in PAT
- knowledge and expertise about PAT

by creating an environment which:

- makes it easy to contact real practitioners
- makes it easy to find relevant information
- promotes the sharing of ideas, information and expertise
- makes it easy to raise issues of common concern to be tackled on a collaborative basis
- serves and supports ISPE's educational and training events
- brings a clear understanding to the boundaries of PAT

Its All About Communication

- **Website (our primary tool)**
- **Web-enabled group working**
- **E-Discussion Forums**
- **Meetings**
- **Conferences**
- **E-Newsletters**
- **Teleconferences**
- **Guides and standards**



[*www.ispe.org/pat*](http://www.ispe.org/pat)

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Education and Training



- Provide input to **educational** themes working in close collaboration with the North American and European Education Committees
- Organize **seminar sessions**
- Provide **speakers and organizers**
- **Interface** with Industry

Newsletter



The PAT CoP newsletter is a regular means of communication featuring:

- **Current activities** the PAT CoP is engaged in
- **Current topics of interest** to the PAT community
- Opportunities to **participate and become involved**
- **Industry updates**
- **Regulatory** changes
- **Forthcoming events, documents, etc.**

Potential Opportunities for Involvement

- Participate in **discussion forums**
- Attend **conference sessions and seminars** on relevant PAT topics
- **Feedback** to the core group interest areas, needs, etc.
- **Access to PAT COP peers** to obtain solutions to real-world problems
- Online and personal **networking** activities

It's not all in place yet

- Help us build our CoP
- Attend conference sessions and seminars on relevant PAT topics
- Take part in discussions, technical reviews
- Supportive software tools being specified
- Articles being reviewed
- Web content being developed
- Help build the Body of Knowledge

Help us build it - Join the PAT COP

To Join the PAT COP You Can:

- Access the PAT COP Web site at www.ispe.org/PAT
- Contact ISPE's Director of Business Initiatives at sludlum@ispe.org