

Introduction of “ISPE D/A/CH”



**Germany/Austria/
Switzerland Affiliate**

ENGINEERING
PHARMACEUTICAL
INNOVATION



International **S**ociety for **P**harmaceutical **E**ngineering (ISPE)
in the Region: **G**ermany, **A**ustria, **S**witzerland (D/A/CH)



Why ISPE?

- **What is ISPE?**
- **Who is organized in ISPE?**
- **What does ISPE International?**
- **What offers ISPE International?**
- **What offers ISPE D/A/CH?**
- **Practical Examples of Workshops**
 - **Linde / Glatt / Pharmatec, Dresden, Sep 2004**
 - **Sartorius , Goettingen, March 2005**
 - **Boehringer Ingelheim / Octapharma, Vienna, Oct 2005**
 - **Schering, Berlin, March 2006**
 - **Nycomed Austria / PAA Laboratories / Red Cross Blood Center, June 2006**
- **CoPs/SIGs (Communities of Practice/Special Interest Groups)**
- **planned Workshops**
- **Advantages on a glance**
- **Contacts**



What is ISPE?

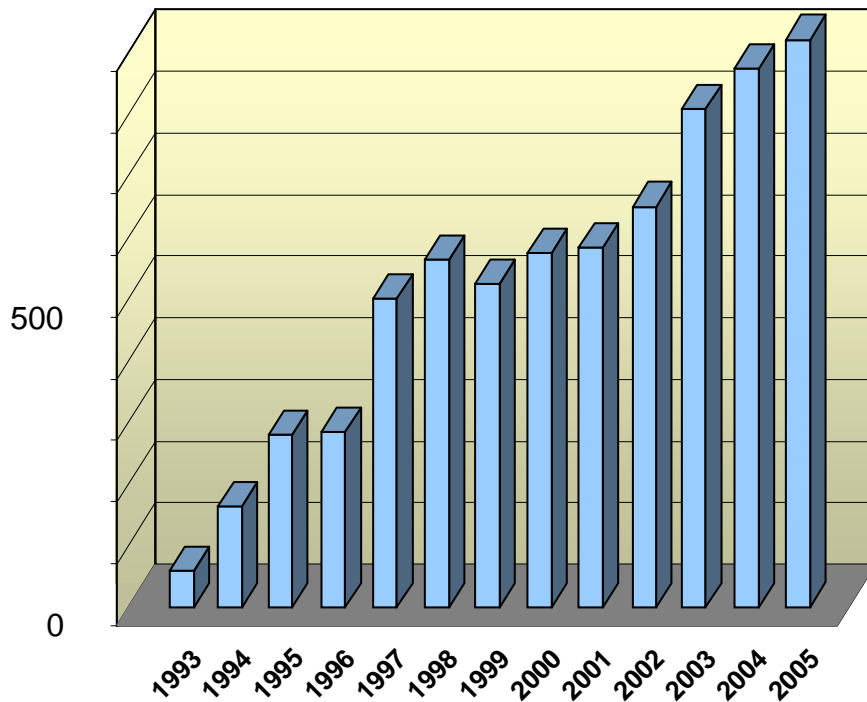
- **ISPE** (International **S**ociety for **P**harmaceutical **E**ngineering) is an independent non-profit-organization, attended to provide training and share of information between employees of the worldwide pharmaceutical industry. In the original concept at its foundation in 1980 the primary focus was on engineering. However, meanwhile the member pattern is composed of all domains of the healthcare system.
- Today ISPE lists over **23.000 members** in more than **80 countries** worldwide and is continuously growing, especially in India, Russia and China.
The German-speaking affiliate **D/A/CH, comprising Germany, Austria and Switzerland counts 1.000 members** presently.
- All **Global Pharmaceutical Companies** are represented in ISPE and give input to decisions in International Committees. ISPE is globally well accepted and a professional partner for all relevant regulatory bodies.
- The **Supply Industry** is represented from the industry sectors machine manufacturing, consulting, instrumentation and facility management.



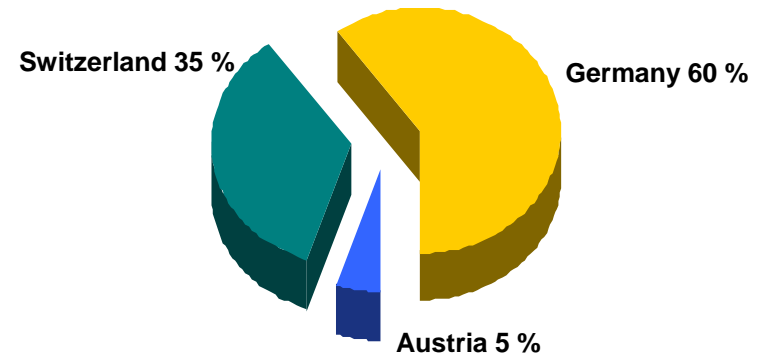
Who is organized in ISPE?

Increase of Membership D/A/CH

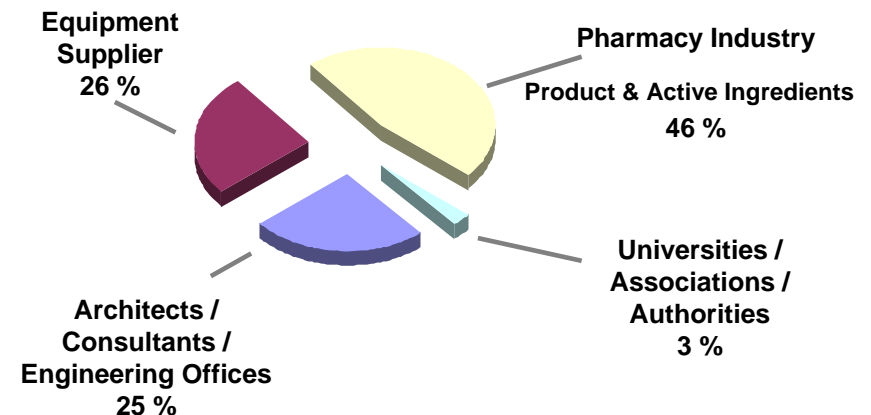
Figures dated from December each Year



Structure of Membership acc. to Countries



Structure of Membership acc. to Sphere of Activity





What does ISPE International ?

- ISPE participates in the **preparation of regulatory guidelines** of FDA and EMEA. As members of ISPE industry representatives get the opportunity to introduce their needs and requirements into the development or revision of regulations.
- ISPE **develops guidance documents** based on regulatory guidelines of the relevant authorities, e.g. FDA and EMEA. These are published as Baseline® Guides.
- Further ISPE activities comprise GAMP* and Good Practice guides addressing various topics such as Process Analytical Technology, compliance, clinical studies and facility design.

* Good Automated Manufacturing Practice



What offers ISPE International ?

- ISPE provides access to **world-wide organized networks**, e.g. technical expert committees.
- ISPE is providing an international platform for exchange of experiences through conferences and seminars organized by ISPE International.
- **International subject matter expert groups** of ISPE support the process optimization initiatives of the pharmaceutical industry, e.g. life-cycle-cost, compliance and time-to-market.



What offers ISPE D/A/CH ?

- **Workshops** with factory visits offer a continuous exchange of experiences.

Example:

Workshop „Packaging and Process Optimization“, held at Schering in Berlin in March 2006. In this event members participated who work for companies as different as:

- | | | |
|------------------------------------|-------------------------|-----------------------------------|
| ⇒ Agilent Technologies | ⇒ Frewitt Printing SA | ⇒ Richter Pharma AG |
| ⇒ August Faller KG | ⇒ GABA International AG | ⇒ Robert Bosch GmbH |
| ⇒ Bayer Healthcare AG | ⇒ Gerhard Schubert GmbH | ⇒ Roche Diagnostics GmbH |
| ⇒ Boehringer Ingelheim Pharma GmbH | ⇒ Glatt GmbH | ⇒ Sanofi-Aventis Deutschland GmbH |
| ⇒ Christ Pharma + Life Science AG | ⇒ Harro Höfliger GmbH | ⇒ Servotech GmbH |
| ⇒ Cilag AG | ⇒ Hochschule Harz | ⇒ Siemens AG |
| ⇒ Dividella AG | ⇒ Lewa GmbH | ⇒ Tuchenhausen GmbH |
| ⇒ Elektrizitäts AG EAGB | ⇒ Merckle GmbH | ⇒ Uhlmann VisioTec GmbH |
| ⇒ Festo AG & Co.KG | ⇒ Nycomed Austria GmbH | ⇒ Werum Software & Systems AG |

as well as for other companies belonging to the services and consulting sector.

- **Interdisciplinary exchange** and active participation in the setting of current and future legal / technical / technological trends.



What offers ISPE D/A/CH ?

- A **knowledge platform** for the exchange of experiences, and thus to leave the limits of daily work.
- ISPE makes associates of pharmaceutical and supply industries speak „**the same language**“. Pharmaceutical and supply industries, planning companies, and universities work on the same questions, such as improvement of economic efficiency, quality and compliance.
- ISPE provides an insight into different **divisions of the pharmaceutical industry**, like research & development, logistics, continuous/batch production for active ingredients/bulk/manufacturing, BioTech, generics, sterile production.
- Provides a base of communication for the exchange of **benchmarks** in order to enlarge company specific experiences.

ISPE D/A/CH 10. Anniversary- Workshop

Linde KCA-Dresden GmbH

Glatt GmbH

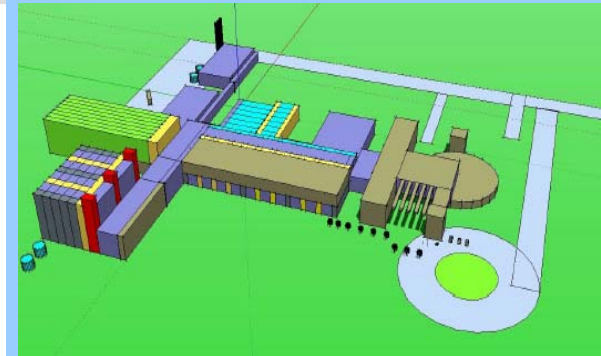
Pharmatec GmbH






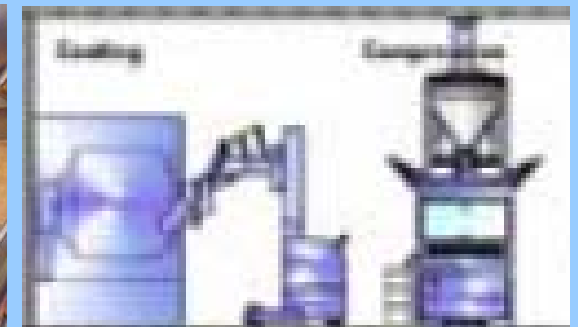
Germany/Austria/
Switzerland **Affiliate**

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Topic	Venue
Engineering Containment Technology Standardization of modular production systems	Germany, Dresden
Date	No. of participants
September 2004	100



Content
 <ul style="list-style-type: none">• „Fast Track“ – Layout development by integrated facility engineering
 <ul style="list-style-type: none">• Standardization of modular production systems
 <ul style="list-style-type: none">• Containment technology



Workshop

Sartorius AG




**Germany/Austria/
Switzerland Affiliate**

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PHARMACEUTICAL
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Thema	Ort
Process Solutions: Upstream und Downstream – Processing	Germany, Göttingen
Zeitraum	Anzahl Teilnehmer
March 2005	50

Inhalt



- Innovative design of Upstream-Processing and efficiency increase in the Downstream-Processing
- Site visit
- Current trends and new solution in the Downstream-Processing
- Integrated validation of biotechnological production
- Fast Track Engineering



Workshop

Boehringer Ingelheim Austria GmbH
Octapharma Wien





Germany/Austria/
Switzerland **Affiliate**

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Topic	Venue
Forschung und Produktion in Österreich	Österreich, Wien
Date	No. of participants
Oktober 2005	50

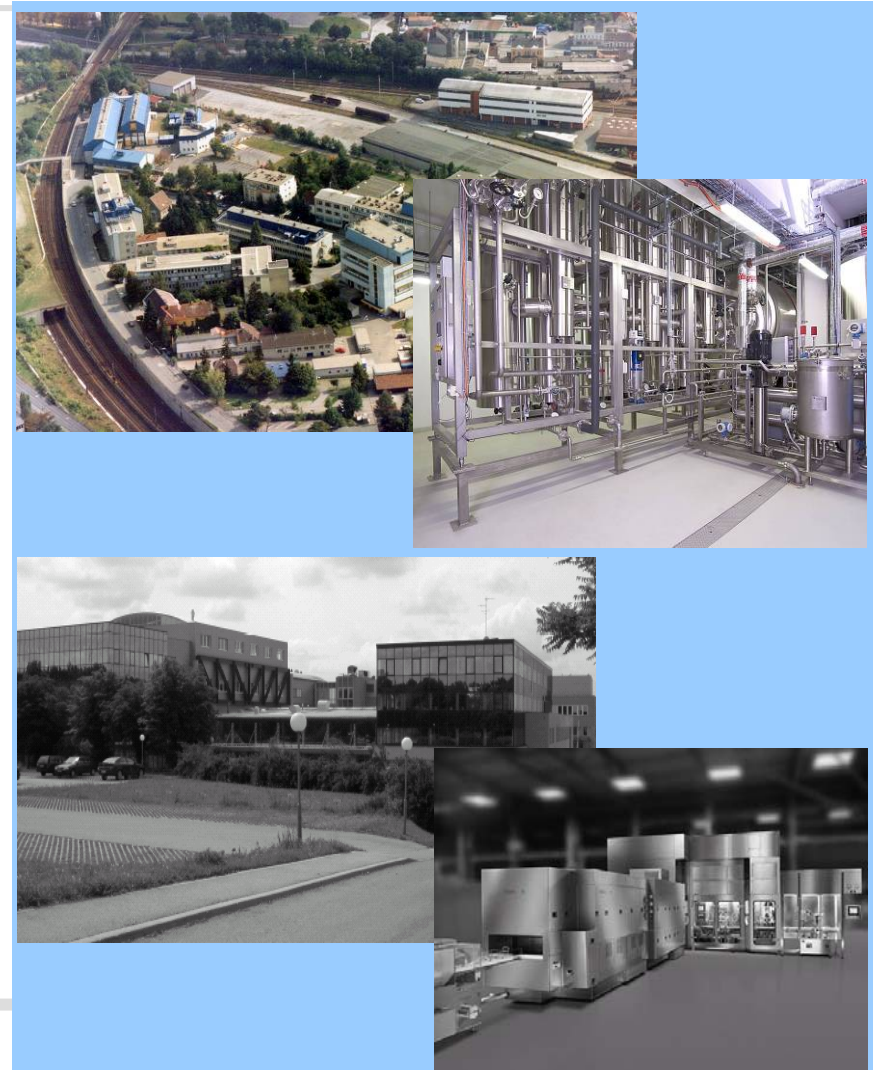
Content

 • Presentation of a biotechnology production (new building project) including site visit of Boehringer Ingelheim in Vienna

 • Presentation of the blood plasma fractionating plant and sterile filling plant including site visit of Octapharma in Vienna

Come Together

- Presentation about the historical development of pharmaceutical industry in Austria
- Presentation „biotechnology in Austria“



Topic	Location
Packaging, efficiency and process optimization	Schering Supply Center, Berlin
Period	Number of participants
March 2006	45

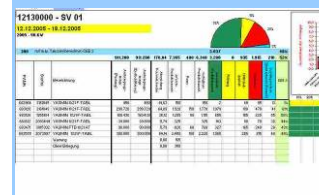
Content



- Efficiency and process optimization in the packaging area using KPIs.
- Zone concepts for optimization of material flow and space-time-recovery.
- New trends in packaging technology.
- Increased anti-counterfeiting
- Tour through the Schering packaging area



Weekly report OEE



Filling line for weekly blister



Workshop

Nycomed Austria GmbH
PAA Laboratories GmbH
Red Cross Blood Centre Linz



ÖSTERREICHISCHES
ROTES KREUZ
OBERÖSTERREICH



Germany/Austria/
Switzerland **Affiliate**

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Topic	Location
Pharmaceutical and Biotechnological industry	Austria, Linz
Period	Number of participants
June 2006	40

Content
<ul style="list-style-type: none">• Presentation of the biotechnological production (extension) incl. a site visit at Nycomed Austria in Linz.• Presentation of the blood bottle manufacturing / cell- & tissue engineering (new building) incl. a site visit at the blood centre in Linz.• Presentation of the GMP compliant production of culture media at PAA in Pasching incl. a site visit.• Speeches:<ul style="list-style-type: none">- Min R. Dr. Johannes Kurz „Advanced Therapy Regulations“- Univ. Prof. DI Dr. Johannes Khinast „Process optimization in the pharmaceutical industry“.





Upcoming Events

You can find upcoming Events like:

Workshop, Professional Discussions, Communities of Practice (CoPs),
etc.

via ISPE home page: <http://www.ispe.org/germany-switzerland>

CoPs (*Community of Practise*)

SIGs (*Special Interest Groups*)



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SIGs within the ISPE provide the participants with the opportunity for discussion and exchange of experience focusing on specific areas of interest. As a result of these discussions, documents will be created which will assist ISPE members when dealing with these topics.

CoP PAT

With the new "risk-based approach" and the PAT Guidance published to outline it, the FDA has started a paradigm change in pharmaceutical manufacturing and control. This entails new challenges for the pharmaceutical industry.

The objective of PAT CoP is to master these challenges with a comprehensive exchange of experience and information among industry, suppliers and regulatory authorities.

The group is internationally represented in ISPE through the ISPE PAT CoP (Community of Practice) Steering Committee which has tight direct contact with the FDA.

Contact: Christian Wölbeling

SIG Water & Steam

The goals of the SIG „Water and Steam“ are to offer guidance with the implementation of the Baseline-Guide Vol. 4 “Water & Steam” as well as to provide input to future volumes of the Guide. The means to these goals are roundtable discussions and workshops held once or twice yearly on topics relating to water and steam chosen by the participants.

Networking with the SIG’s in other affiliates will enable an international exchange of ideas and experiences.

Contact: Löhe, Tanja and Christian Stark,



All advantages at a glance

- ⇒ Information of the current status and trends in the pharmaceutical industries, market information and international contacts inclusive. ISPE member will receive the **journal PHARMACEUTICAL ENGINEERING** (6 x per year) and access to the **On-Line Archive**
- ⇒ Constant exchange of experiences during **Workshops, Site visits and CoPs/SIGs** (Communities of Practise/Special Interest Groups, e.g. Water, PAT) within ISPE D/A/CH
- ⇒ Assure **Seminars for further education** within ISPE Europe. ISPE members will get discount for all ISPE-Conferences, – Congresses, -Seminars and –Training courses
- ⇒ Exclusive access for all members to the ISPE-Website with **special platforms for discussion and downloads free of charge**
- ⇒ Rebates within purchasing of **Technical Literature** (GAMP, Baselines)
- ⇒ Provide access to the register of ISPE members (about 23.000) in approx. 80 countries.

Contact data



**Germany/Austria/
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ISPE D/A/CH can be contacted via its homepage: <http://www.ispe.org/germany-switzerland>. If you are interested in ISPE or have questions about ISPE, you can also get in touch with the Board/Committee direct. The geographical distribution of our Board/Committee members will surely create the opportunity for you to arrange for a personal discussion.

Board					
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Vice Chair	Dr. Fischer, Wolfgang	Bayer HealthCare AG	+49 (0) 214 3037871	wolfgang.fischer@bayerhealthcare.com	D - Wuppertal
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D/A/CH Affiliate Manager	European Office, Brussels, Belgium	ISPE Headquarter, Tampa, USA
Rolf Sopp +49 (0) 177- 4620641 eMail: Rolf.Sopp@onlinehome.de	Tel: 32-2-7-743-44-22 eMail: ispe@associationhq.com	Tel: 1-813-960-2105 Homepage: www.ispe.org eMail: customerservice@ispe.org



What does ISPE cost?

Standard membership:

- 190 € in the first year
- 150 € in subsequent years

Special membership:

- 30 €/ year full-time employees of state organizations (supervisory authorities, public bodies,...)
- 30 €/ year full-time employees of educational institutions (universities, technical colleges,...)
- 15 €/ year for students

Member Information (Please print clearly)

Prefix _____ First Name (no initials) _____ Middle Initial _____ Last Name _____

Informal Name / Name to be used on name badge _____

Gender Female Male _____ Job / Occupation Title _____

Company Name or Organization _____

Check Mail Preference

→ Business Street Address _____

Suite _____

PO Box _____

Mail Stop Code _____

City or Suburb _____

State / Province _____

Zip+4 / Postcode _____

Country _____

Business Telephone _____

Business Fax _____

Business E-mail Address _____

→ Home Address (for office use only) _____

City or Suburb _____

Apartment _____

State / Province _____

Zip+4 / Postcode _____

Home Telephone _____

Home Fax _____

Mobile (optional) _____

Alma Mater _____

Home E-mail Address _____

- I wish to keep my data confidential and only used by ISPE and its local Affiliates and Chapters.
 I **DO NOT** want to be included in the Membership Directory or Conference Attendee listings.

International Affiliates (select one)

Network with industry and regulators in your region and attend local events with your complimentary membership in an ISPE Affiliate or Chapter.
Visit www.ispe.org/Affiliates_Chapters for more information.

- Argentina
 Australasia (or select one Chapter)
 Brisbane
 Melbourne
 New Zealand
 Sydney
 Belgium
 Brazil
 Canada
 Central Canada
 Czech Republic/Slovakia
 France
 Germany/Austria/Switzerland
 India
 Ireland
 Italy
 Japan
 The Netherlands
 Nordic (Sweden, Denmark, Norway, Finland, and Iceland)
 Poland
 Singapore
 Spain
 Thailand
 Turkey

United Kingdom (check one Region)

- Central
 North East
 North West
 Scotland
 Southern

United States of America (check one Chapter)

- Boston Area (Eastern Massachusetts, Maine, and New Hampshire)
 Carolina-South Atlantic (North and South Carolina, Georgia, Florida, Alabama, and Tennessee)
 Chesapeake Bay Area (Maryland, Washington, DC, and Northern Virginia)
 Delaware Valley (Eastern Pennsylvania, Southern New Jersey, and Delaware)
 Great Lakes (Ohio, Indiana, Illinois, Michigan, Wisconsin, and Kentucky)
 Greater Los Angeles (Los Angeles, Orange, Ventura, and Riverside Counties)
 Midwest (Missouri, Kansas, Nebraska, Iowa, and Minnesota)
 New England (Connecticut, Western Massachusetts, Rhode Island, Eastern and Upstate New York, Vermont and New Hampshire)
 New Jersey (New Jersey, New York, and Northeast Pennsylvania)
 Pacific Northwest (Washington and Oregon)
 Puerto Rico (Puerto Rico)
 Rocky Mountain (Colorado, Utah)
 San Diego (San Diego north to south Orange County)
 San Francisco Bay Area (Northern California)
 South Central (Texas, Oklahoma, and Louisiana)

I do not wish to join an Affiliate or Chapter

WHAT IS YOUR PRIMARY COMPANY TYPE?
(select one)

- Manufacturer/Operating**
- 1. Traditional Pharmaceuticals
 - 2. Biopharmaceuticals/Biotechnology
 - 3. Contract
 - 4. Generic
 - 5. Veterinary Medicine
 - 6. Medical Devices/Diagnostics
 - 7. Bulk/API
 - 8. Cosmetics
 - 9. Food/Nutraceuticals
- Service Provider**
- 10. Engineering/Architecture
 - 11. Consulting
 - 12. Validation/Qualification/Commissioning
 - 13. CRO - Clinical or Contract Research
 - 14. Construction Services Contractor
 - 15. Facilities/Equipment Maintenance
 - 16. IT/Computer Services

Supplier

- 17. Equipment/Components
- 18. Packaging Materials
- 19. Clinical/Investigational Materials
- 20. Software/Hardware Products
- 21. Chemicals/Intermediates

Academia

- 22. Academia

Public Authority/Government

- 23. Public Authority/Government

- 99. Other: _____

WHAT IS YOUR PRIMARY AREA OF EXPERTISE?
(select one)

- A. Architect/Engineer/Construction
- B. Clinical/Investigational Materials
- C. Health/Safety/Environmental
- D. Information Technology
- E. Logistics/Supply Chain Management
- F. Maintenance
- G. Operations/Manufacturing
- H. Process Control/Automation
- I. Process Development/Technology Transfer
- J. Project Management
- K. Quality Assurance/Control
- L. Regulatory/Compliance
- M. Research and Development
- N. Sales/Marketing/Business Development
- O. Technical Services/Product Support
- P. Training
- Q. Validation/Qualification/Commissioning
- ZZ. Other: _____

YEARS IN INDUSTRY:

- 1-4
- 5-14
- 15-19
- 20 and more years

I hereby apply for membership in ISPE and certify that all statements made in this application are correct, and if elected to membership, agree to be governed by the Society Bylaws.

Applicant's Signature _____

Referring Member Name _____

Date _____

ID# _____

MEMBERSHIP CATEGORIES AND PAYMENT INFORMATION

All Members of ISPE are entitled to vote on matters pending before the Society, hold office, and serve on committees. Memberships are individual and not transferable. For membership category descriptions, bylaws, and the Student Membership Application, visit www.ispe.org/membership.

Active Members:

- US Dollars \$200
- Euros €190
- \$160/€160 annual dues plus \$40/€40 administration fee. \$60/€60 of your dues is allocated to your subscription to *Pharmaceutical Engineering* magazine.

Public Authority/Government Members:

- US Dollars \$30*
- Euros €30*

Academic Institutional Members:

- US Dollars \$30*
- Euros €30*

Emerging Economy Members: Visit www.ispe.org/emergingeconomy for a list of eligible countries. Membership includes

Members-only access to the ISPE Web site and on-line access to *Pharmaceutical Engineering* magazine.

- US Dollars \$30
- Euros €30

Payment or credit card information MUST accompany application. No purchase orders accepted. FEI #59-2009272

- Check enclosed payable to ISPE # _____ (drawn on a US bank) or € _____

- Credit Card Type: VISA MC/EUROCARD AMEX

Card Number _____

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Cardholder Signature _____

ISPE Headquarters

(US Dollars Accepted)

3109 W. Dr. Martin Luther King, Jr. Blvd.
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Tampa, Florida 33607 USA

Tel: +1-813-960-2106

Fax: +1-813-264-2816

E-mail: customerservice@ispe.org

ISPE European Office

(Euros Accepted)

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Fax: +32-2-743-1550

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ISPE Asia Pacific Office

(US Dollars Accepted)

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Singapore 229632

Tel: +65-6330-6755

Fax: +65-6336-2263

E-mail: asiapacific@ispe.org

* \$15/€15 of your dues is allocated to your subscription to *Pharmaceutical Engineering*.

Prices good through 31 December 2007, after 31 December 2007, please contact ISPE for current rates. Members may not deduct the subscription price from dues.

Student Information (Please print clearly)

Prefix _____ First Name (No initials) _____ Middle Initial _____ Last Name _____

Informal Name (Name to be used on name badge) _____

Gender Female Male

Job / Occupation Title _____

University/College _____ Expected Date of Graduation (Required) _____

Company Name or Organization _____

Check Mail Preference

Permanent Address (Required)

P.O. Box _____ Suite _____

City or Suburb _____ Mail Stop Code _____

Zip+4 / Postcode _____ State / Province _____

Telephone _____ Country _____

E-mail Address _____ Fax _____

Alternate Address (Required) (For office use only)

City or Suburb _____ Apartment _____

State / Province _____ Zip+4 / Postcode _____

Telephone _____ Fax _____

Mobile (Optional) _____

E-mail Address _____

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 - Czech Republic/Slovakia
- France
- Germany/Austria/Switzerland
- India
- Ireland
- Italy
- Japan
- The Netherlands
- Nordic (Sweden, Denmark, Norway, Finland, and Iceland)
- Poland
- Singapore
- Spain
- Thailand
- Turkey

- United Kingdom (Check one region)
 - Central
 - North East
 - North West
 - Scotland
 - Southern

- United States of America (Check one Chapter)
 - Boston Area (Eastern Massachusetts, Maine, and New Hampshire)
 - Carolina-South Atlantic (North and South Carolina, Georgia, Florida, Alabama, and Tennessee)
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 E. Logistics/Supply Chain Management
 F. Maintenance
 G. Operations/Manufacturing
 H. Process Control/Automation
 I. Project Development/Technology Transfer
 J. Project Management
 K. Quality Assurance/Control
 L. Regulatory/Compliance
 M. Research and Development
 N. Sales/Marketing/Business Development
 O. Technical Services/Product Support
 P. Training
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Date _____

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Emerging Economy Students: Individual Students residing in an emerging economy country may receive a discount on dues through the local ISPE Affiliate. For a list of eligible countries, please visit www.ispe.org/mergingeconomylist. Please contact the local ISPE Affiliate in your area for complete details and rates.

- US Dollars \$15

- Euros €15

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 King Jr. Blvd., Suite 250
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ISPE European Office

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 E-mail: ispe@associationhq.com

ISPE Asia Pacific Office

(US Dollars Accepted)
 73 Bukit Timah Road
 Singapore 229832
 Tel: +65-6330-6755
 Fax: +65-6336-2263
 E-mail: asiapacific@ispe.org

Application Checklist:

- Fully completed membership application
 Payment
 Proof of full-time student status

Acceptable Proof:

Current semester schedule showing number of credits.
 Transcript (official or unofficial) with number of current credits.
 University letter stating "full-time student".
 University Web site page stating the date and "full-time student"