



Historical Timeline

1980

- In August 1980, a group of six men met at American Airlines' Admiral Club at La Guardia airport to discuss the formation of an engineering society whose primary purpose would be focused on:
 - Education
 - Networking
 - Exchange of information
- The conception of the Society continued to unfold as validation became more and more of a reality with an expanded need for consistency within the industry.
- Formation of the Society was complete when the name "International Society of Pharmaceutical Engineers" was decided upon.
- There were three staff members when ISPE began: Diane Simmons, Executive Director/Editor; C. David Boyer, Managing Editor; and Cheryl A. Conroy, Administrative Assistant.
- The first issue of *Pharmaceutical Engineering* (November 1980 - January 1981) was published. This quarterly publication was known as the "Official Journal of ISPE."
- The 1980 Board of Directors included:
 - Charles W. Newcomb – President
 - Paul Simmons – Executive Vice President
 - James O'Brien – Vice President
 - Peter A. Merrett – Treasurer
 - Thomas P. Henry – Secretary

1981

- ISPE's relationship with the FDA began in 1981 when the Society asked the FDA to speak at a seminar.
- The first official seminar took place in February 1981 at the Tampa Host Hotel and was attended by 106 people. The panel of speakers included representatives from the US Food and Drug Administration as well as professionals in the industry. The topic of the seminar was "Upgrading to Meet cGMPs."
- In the first year membership grew to 430.
- The first Annual Membership Meeting and Awards Banquet was held 11 November 1981 in the Warwick Hotel, Philadelphia, Pennsylvania and was attended by more guests than paying attendees. The Meeting was held in conjunction with PACK INFO '81, 11-12 November at the Philadelphia Civic Center.



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1982

- Ron Hall became Executive Director in 1982.
- *Pharmaceutical Engineering* began to publish bi-monthly with the July/August 1982 issue.

1985

- Bob Best became ISPE's Executive Director in 1985.
- ISPE began to publish a newsletter for Members only.
- ISPE Expo was held for the first time in Philadelphia in June 1985.
- At the ISPE Annual Meeting in November 1985 a steering committee was formed to determine the interest and feasibility of creating a local chapter in New Jersey. The effort ended successfully and **ISPE's first North American Chapter was chartered in New Jersey in late 1986.**¹

1986

- ISPE sponsored its first International Pharmaceutical Engineering Forum during the 1986 Annual Meeting held 16-19 November in St. Petersburg Beach, Florida.
- Membership grew to 1,000 in 1986.

1989

- ISPE's first European venture, the International Congress of Pharmaceutical Engineering, took place on 26-28 September 1989 at the Scandic Crown Regency Hotel in Brussels.
- The **first two European Affiliates** were formed in 1989-1990 in the United Kingdom and Ireland.

1990

- In 1990 the Society name was changed slightly from "International Society of Pharmaceutical Engineers" to "International Society for Pharmaceutical Engineering."
- Staff grew to nine employees.

¹ Today ISPE has 39 Affiliates and Chapters throughout the world. In addition, several large Affiliates have Chapters, i.e., semi-independent subgroups, within them. In the interest of space and clarity, only the various "firsts" are listed in this history.



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- ISPEAK was unanimously chosen by the ISPE Editorial Committee as the official name of the ISPE newsletter in March 1990. The name was chosen as a result of a “Name the Newsletter” competition won by Thomas J. Novitsky of Associates of Cape Cod.

1991

- **The New Jersey Institute of Technology became ISPE’s first official Student Chapter** at a dinner meeting held on 24 February 1991.

1992

- ISPE opened a European office in the Hague, Netherlands in 1992 and added six more employees to the total.
- In 1992, volunteer leaders from North America and Europe wrote the first strategic plan and mission statement for the Society.

1993

- In February 1993, ISPE implemented strategic objectives by establishing North American and European Operating Committees.
- The **Germany/Switzerland Affiliate was ISPE’s first multi-national Affiliate** and organized its first programs in 1993. Unlike other ISPE Affiliates, this group is organized not nationally, but regionally, holding meetings in southwestern Germany and northern Switzerland. Later, Austria became the third nation served by this group – the DACH Affiliate.
- ISPE membership reached 5,000.

1994

- In 1994, industry leaders developed industry-wide guidance for suppliers to assist in the management and development of computer systems. The result was the GAMP Guide which is now in its fifth edition. More than 10,000 copies have been distributed globally in four different languages.

1995

- The Career Center was begun in 1995. Today it is known as “Career Solutions,” and encompasses a variety of offerings to help Members navigate through the many decisions that encompass a career in the industry.



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- At the 1995 Annual Meeting, ISPE introduced the Pharmaceutical Engineering Baseline[®] Guide Series with the draft of Volume 1, Bulk Pharmaceutical Chemical Facilities.

1996

- ISPE held its first event in Australia on 20-22 May, 1996 at the Hyatt Regency Hotel in Canberra. The program was titled “International Regulatory Trends in the Pharmaceutical Industry.” **Shortly after this, the Australasia Affiliate was chartered, ISPE’s first Affiliate in the Pacific region.**
- During the ISPE Pharmaceutical Advisory Council (PAC) meeting 4 June 1996 in Valley Forge, a presentation was made by the FDA’s Matthew Lewis, District Director, and Joseph Phillips, Deputy Regional Food and Drug Director, proposing another partnership effort between ISPE and FDA. In this project, ISPE committed to develop the list of equipment, by functionality categories, to specify similar equipment as referenced by the new Scale-Up and Post-Approval Changes (SUPAC) regulations. SUPAC is one of the most significant regulatory changes ever to benefit the industry. SUPAC gives guidance to aid the industry on how to file and significantly reduces the filing burden in many circumstances. Some changes that once needed an approved supplement might now properly be submitted as a change being effected or in the next annual report under SUPAC terms. Determining similar equipment was the task that the FDA asked ISPE to undertake.
- In response to Member demand, ISPE created its Web site, www.ispe.org, which was live as of 1 November 1996.
- ISPE re-designed the organization’s logo to better show the Society as “international” in scope.

1997

- As reported in the January/February 1997 issue of *Pharmaceutical Engineering*, ISPE signed an agreement with Reed Exhibition Companies as official sponsor of INTERPHEX events. Said ISPE’s President Larry Kranking at the time of the partnership: “INTERPHEX has long been the trade show of choice for most ISPE members.”
- As reported in the July 1997 issue of *ISPEAK*, Sharon Smith Holston, Deputy Commissioner for External Affairs, FDA, presented the FDA Commissioner’s Special Citation “in appreciation of outstanding cooperation with the Food and Drug Administration in providing vital support to the industry through educational and special projects, nationally and internationally.” Bob Best accepted the award on behalf of ISPE and received the Harvey W. Wiley Medal, the father of the Pure Food and Drug Law.



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- At the 1997 Annual Meeting, ISPE was honored with Vice President Al Gore's Hammer Award that was presented to the ISPE-FDA team that developed a list of "similar equipment" needed for efficient implementation of Scale-Up and Post-Approval Changes (SUPAC) guidance for products in immediate release – solid dosage form.
- On 21 November 1997, ISPE was honored by the Center for Drug Evaluation and Research (CDER) with a special Recognition Award.

1998

- On 7 October 1998 ISPE held its first official activity in South America (Brazil) in conjunction with the launch of Reed Exhibition Companies' INTERPHEX South America trade show. The event was attended by more than 100 industry professionals. **Shortly after this, the Brazil Affiliate was chartered, ISPE's first South American Affiliate.**

1999

- In 1999, the ISPE European Office in The Hague closed. ISPE established a relationship with an association management company (GIC; today MCI) and opened an office in Brussels, Belgium which is operating today.
- ISPE sponsored the first INTERPHEX Japan in 1999.
- The first global edition of ISPEAK was published in July/August 1999.

2000

- ISPE staff reached 31 employees in 2000.
- ISPE acquired the GMP Institute effective 1 January 2000 and began ISPE's training division.
- The first educational conference in Singapore took place 12-13 June 2000 at the Pan Pacific Hotel in conjunction with Reed Singapore. This was the first educational conference in Asia.
- **In June 2000, the ISPE Singapore Affiliate was officially launched and was the first Affiliate in Asia.**



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2002

- The U.S. Department of Commerce chose ISPE to offer a four-week intensive training program jointly led by the GMP Institute, consultant Dale McMillen, and the American Association for the Advancement of Science (AAS) from 14 January to 8 February 2002. The course provided basic knowledge and training on current Good Manufacturing Practices (GMPs) to enable former bio-chemical scientists from the Novosibirsk region of Russia to adapt from their current manufacturing standards to internationally acceptable manufacturing practices.

2003

- *Pharmaceutical Engineering* introduced a new feature, Country Profile, highlighting the pharmaceutical industry in countries where an international ISPE Affiliate exists; this feature has been expanded in 2005 to include North America.
- In 2003, the ISPE International Board of Directors approved the new emerging economy membership category.

2004

- ISPE reached 20,000 Members in 2004.

2005

- In April 2005, Danish pharmaceutical company Novo Nordisk A/S was named the first Facility of the Year Award winner at the INTERPHEX 2005 Conference and Exhibition at the Jacob K. Javits Convention Center in New York City. Novo Nordisk was chosen for its new NovoSeven® pharmaceutical manufacturing facility in Hillerød, Denmark, winning out over a global field of 28 entries representing 12 countries. Novo Nordisk won among four other finalists: Alkermes, Inc. of Cambridge, Massachusetts; Apotex, Inc. of Toronto, Ontario, Canada; Kowa Company, Ltd. of Nagoya, Japan; and Lundbeck, Ltd. of the United Kingdom.
- In July 2005 ISPE opened an office in Singapore to serve Members and local Affiliates in the Asia Pacific region.
- September 2005, in cooperation with the US Food and Drug Administration (FDA), ISPE released a definition paper on restricted access barrier systems (RABS). The paper provides a definition of RABS for the Agency and the pharmaceutical industry, with the goal of reducing confusion about the key elements of RABS and their regulatory requirements.



Historical Timeline

- The FDA invited ISPE to play a leading role in its transition to changing the way it has regulated the industry for decades and in the incentives being offered to companies to innovate. Specifically, the FDA is asked ISPE to change its current operating procedure in several ways:
 - Publish a new science-based, peer-reviewed journal.
 - In collaboration with universities and the FDA, develop a training program to be utilized by both Industry and Regulators;
 - Establish a Certification program that sets a standard for Pharmaceutical Manufacturing Science and Technology competency;
 - Work through ASTM to establish standards that must be referenced by the FDA.
- In November 2005, ISPE launched the formation of ISPE Communities of Practice. Six new pharmaceutical manufacturing Communities of Practice (COPs) were announced at ISPE's 25th Anniversary Annual Meeting. ISPE Communities of Practice are groups of like-minded professionals who have come together to actively share ideas and solve problems within a specific field or emerging trend of the pharmaceutical industry. ISPE COPs have formed around the following disciplines: active pharmaceutical ingredients (APIs), commissioning and qualification (C&Q), biotechnology, product/process development, process analytical technology (PAT), sterile products processing, and critical utilities.
- The culmination of ISPE's 25th anniversary celebration took place at the 2005 Annual Meeting in November. ISPE received the Commissioner's Special Citation from the US Food and Drug Administration (FDA). Dr. Janet Woodcock, the FDA's Deputy Commissioner of Operations, made the presentation to incoming ISPE Chairman Gert Moelgaard. The presentation was made in recognition of ISPE's "outstanding commitment and many years of continued support of crucial initiatives including the drug shortage program, the Process Analytical Technology Initiative, the reform of 21 CFR Part 11, and the Risk Based Inspection Model, as well as significant contributions to preparing for training the pharmaceutical professionals of the future."

2006

- January 2006, ISPE's Professional Certification Commission (PCC) launched an international job analysis survey, designed to solicit input from 1,200 randomly selected pharmaceutical professionals. The survey was one of the first steps in the PCC's effort to develop a professional credential for pharmaceutical practitioners.
- ISPE redesigned its website and logo.



Historical Timeline

- In March 2006, ISPE joined forces with the University of Florida in an effort to train workers for Florida's growing biotechnology industry. The partnership helped train instructors and develop coursework that is useful and appealing to high school and college students, as well as to workers interested in switching to entry and mid-level careers in the biotechnology industry.
- ISPE launched E-Letter series based on Communities of Practice.
- ISPE published the inaugural electronic version of ISPEAK.
- ISPE published the premier issue of the *Journal of Pharmaceutical Innovation*, with editor James Drennen III in September 2006.
- ISPE co-hosted its first conference with PDA about ICH guidances.

2007

- The PCC held the first examination for its CPIP credential.
- ISPE created the Product Quality Lifecycle Implementation (PQLI) initiative and held the first workshops in Washington. At least 230 delegates and regulators attended. PQLI was followed up in Berlin and Las Vegas later in the year.
- ISPE launched a new web application for its 14 COPs.

2008

- GAMP 5 was launched to a sell-out crowd at the Spring Conference in Copenhagen.
- ISPE continued to make progress in Asia. In 2008 the Society opened its Shanghai office, the Steering Committee working to form a China Affiliate grew to include more than 30 people, nearly 100 students from Sichuan University became Members, and the Society hosted a successful two-day event in Beijing with its partner CCPIE.
- Membership peaked at 24,414.



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2009

- The global financial crisis affected ISPE and its Members.
- ISPE began to re-invent itself for the new realities. Accordingly, the Society began offering technology-based learning and reaching out to Members through social media channels.
- The Nordic Affiliate pioneered the first CPIP study group, a model that has been replicated in numerous Affiliates and Chapters since that time.

2010

- In response to changing needs, ISPE launched the Membership Value Project (MVP). MVP is a series of initiatives to help Members - as individuals - connect with the value they receive from ISPE membership. Included are a monthly package of free gifts including webinars, document chapters, and online tools; a completely redesigned Career Solutions Center online, a series of free virtual events for Members, and the ability to keep membership current at no cost when a Member is out of work. Member retention has steadily improved as a result.
- To strengthen and grow the involvement of global regulators, ISPE introduced complimentary membership for these professionals.
- ISPE began organizing its Young Professionals initiative and aimed to close the gap between its robust student programs and the mid-career professional who is ISPE's "typical" Member.
- ISPE clearly defined its core Members, segmented them and began to study their needs. The Society also studied its own core competencies, and both resulted in a series of activities aimed at improving the Society's alignment with Members' needs and priorities.

2011

- ISPE continued to build on its Young Professionals initiative by introducing a special membership rate and providing toolkits for Affiliates/Chapters to create strong, active YP programs locally.
- ISPE developed a new Strategic Plan for 2012-2015
- ISPE launched a dramatically improved website.
- CPIP was re-launched. While preserving the integrity of the competency-based credential, the PCC dramatically reduced the administrative burden and barriers to taking the exam.
- Bob Best announced his retirement after 27 years of service to ISPE.
- In December, Nancy Berg was named ISPE's new President and CEO.