



**Connecting a World of
Pharmaceutical Knowledge**

International Society for Pharmaceutical Engineering

President/Chief Executive Officer Position Profile March 2014

This profile provides information about the International Society for Pharmaceutical Engineering (ISPE) and the position of President/Chief Executive Officer. The profile is designed to assist individuals in assessing their interest in and qualifications for the position.

The search for the President/Chief Executive Officer of ISPE is being conducted by Association Strategies, Inc., 1111 North Fairfax Street, Alexandria, VA 22314 (www.assnstrategies.com). Interested candidates may apply at http://www.assnstrategies.com/current_searches.php.

To learn more about ISPE, go to www.ispe.org. The deadline for applications is April 15, 2014.

President/Chief Executive Officer Position Profile **for the International Society for Pharmaceutical Engineering**

Profile Methodology

The profile for the position of President/CEO of the International Society for Pharmaceutical Engineering (ISPE) was developed using organizational data; discussions with key stakeholders, industry partners, representatives of regulatory agencies and staff; and responses to an online survey of volunteer leaders. This outreach was conducted to identify and prioritize the skills, knowledge, experience, qualifications and qualities required and desired in a President/CEO. Information regarding programs and services, organizational and cultural factors, and challenges and opportunities for ISPE was also developed from the survey responses and discussions.

About ISPE

ISPE, a 501(c)(6) organization, was founded in 1980 and is the world's largest nonprofit association dedicated to advancing pharmaceutical and bio-pharmaceutical manufacturing, key supporting functions and supplier professionals, and to serving as the catalyst for solutions that influence global public health. The organization leads relevant dialogue on major industry issues affecting companies and health authorities, fosters expertise and knowledge, and is viewed by manufacturing professionals and regulators worldwide as the premier source for information. The majority of the ISPE staff is headquartered in Tampa, Florida; however, the President/CEO will be based primarily in Washington, D.C. (with frequent travel to Tampa), in order to establish a strong headquarters presence for the organization there, and will be responsible for overseeing and managing the eventual transition of selected organizational activities from Tampa to Washington, D.C.

ISPE serves more than 22,000 members in 90 countries, including company leaders, global regulators and individuals working in the fields of quality systems, facility design and maintenance engineering; investigational products; supply chain; manufacturing operations; process development; tech transfer; regulatory affairs; training; materials management; marketing and sales; purchasing; qualification; validation; equipment; and pharmaceutical services. Members and stakeholders include pharmaceutical, biotechnology and medical device firms; diagnostic manufacturers; architecture, engineering and construction firms serving the industry; government agencies; universities; equipment manufacturers; and suppliers. ISPE provides its members opportunities to develop their technical knowledge, exchange practical experience within their communities, enhance their professional skills, and collaborate with global regulatory agencies and industry leaders. Because ISPE does not engage

in lobbying activities and makes no attempt to influence regulations for reasons other than the need for current best technical practice, the Society plays a vital role in designing, debating and publicizing more effective processes and standards through robust and evidence-based dialogue. ISPE's neutral environment ensures that these activities are based on the application of sound scientific and technological principles through the expert contributions of individual members, regardless of their employer, status or affiliation. A further benefit of this neutrality is a cordial and effective working relationship with regulators globally.

President/CEO Position

Responsibilities: In collaboration with the International Board of Directors, the President/CEO is responsible for providing leadership on matters of governance, mission, vision and strategy; safeguarding and enhancing the financial stability and resources of the organization; developing and managing the international professional staff; overseeing all Society activities and operations; serving as the primary liaison with governmental and regulatory agencies worldwide and pharmaceutical industry leadership (including manufacturers, suppliers and service providers); maintaining an effective public relations program; and serving as the official spokesperson for the Society. This is an execution, financial control and marketing oversight role demanding the full skill set associated with a CEO position, focused on creating a strong organization that supports individual members and high-level industry needs.

Education and Experience: The ideal candidate will have a Bachelor's degree (a Master's degree in business administration is considered an asset); a minimum of 10 years of executive or senior-level management experience in association management in the healthcare, medical, science, technology, engineering or pharmaceutical industries (or comparable experience in pharmaceutical organizations); demonstrated success in fiscal responsibility and financial expertise; and experience in transforming the influence, role and profile of an organization. Previous experience as a CEO or COO is an asset but is not required. The successful candidate will be a relationship builder who understands and can enhance ISPE's critical role in the regulatory space, and will have demonstrated skills in organizational direction shift – an agent for changing times.

The ideal candidate will demonstrate experience and success in the following areas:

1. Effectively applying financial and business acumen to ensure short- and long-term stability of an organization's assets, including development and diversification of sustainable revenue sources;
2. Developing and implementing strategic business plans and initiatives, and identifying and prioritizing short- and long-term organizational goals, needs and resources;

3. Displaying exceptional proficiency in public speaking;
4. Employing effective public relations and taking a leadership role in enhancing the profile, reputation and influence of an organization among external and internal audiences;
5. Identifying and capitalizing on market trends and leveraging an organization's resources and influence;
6. Leading and managing a large, visible and complex association, its governance issues and structures, and serving as an ambassador for an organization and industry;
7. Understanding and providing leadership to ensure that programs, activities and services reflect the diversity of members of an international organization, with attention to international cultural processes, customs, regulations, systems and communications;
8. Establishing and strengthening operations, communications systems and processes in a complex and diverse organization;
9. Developing, managing and motivating a high-functioning professional staff and an effective relationship with a Board of Directors, and creating a positive culture throughout the staff and the Society;
10. Marketing the value of a membership organization;
11. Strengthening relationships with chapters and affiliated organizations, with demonstrated recognition of both their common and unique needs;
12. Building and maintaining strategic partnerships with related organizations, and expanding global reach and international relevance; and
13. Interacting with governmental agencies.

Other highly desirable experience includes increasing membership and member retention; creating and delivering membership training and development; developing and delivering innovative association services, programs, education and resources; and understanding and knowledge of pharmaceutical chemistry, manufacturing and controls (CMC) and good manufacturing practices (GMP).

Skills and Abilities: The following are important to the candidate's success in the position of President/CEO:

1. Visionary leadership and foresight in order to capitalize on opportunities, identify challenges, anticipate and respond to course changes, and secure the resources necessary for organizational success;
2. Strong interpersonal, written and oral communications skills, with the ability to deliver clear and effective messages to all stakeholders;
3. Ability to build consensus among diverse constituencies and related organizations in order to further common goals and objectives and to leverage resources and influence;

4. Knowledge and implementation of best practices in association management; and
5. Demonstrated success in implementing organizational change and financial management.

Personal Characteristics and Behaviors: The President/CEO will possess the following personal characteristics and behaviors:

1. Inclusive, collaborative and collegial; a team-builder and consensus-builder;
2. Visionary, innovative, and creative;
3. Open-minded and forward-thinking;
4. Engaging, personable, accessible and motivational;
5. Confident, thoughtful, poised and professional, with a sense of humility;
6. Respectful of opposing points of view and differences of opinion;
7. Aware of and sensitive to international cultural differences and able to infuse such qualities in staff and member activities;
8. Effective and efficient decision-maker;
9. Process-driven, attentive to detail and analytical;
10. Open to working with and learning from others who have skill sets different from his/her own; and
11. Builder of strong, integrated teams of key support staff who are leaders in their own fields.

Measures of Success

The President/CEO's success in the position will be measured by demonstrated progress in the following areas:

1. Growth, management and stability of the organization's financial resources and membership;
2. Enhancement of the leadership role and public profile of the organization;
3. Quality of relationships and collaboration with volunteer leaders (i.e., Board of Directors, committee chairs), members, chapters, affiliates, regulators and related organizations;
4. Identification of an effective business model that is well-communicated to the membership and implemented by the staff;
5. Assessment and enhancement of the culture of the organization;
6. Advancement and implementation of the organization's strategic plan;
7. Development, engagement and motivation of the professional staff;
8. Demonstration of the ability to listen carefully to all constituencies and develop an understanding of their concerns, issues and needs;
9. Establishment and enhancement of strong relationships with regulatory organizations and agencies; and

10. Initiation of interaction and development of relationships with chapters and affiliates through local meetings and improved coordination and communications.

Structure, Governance and Staff

The President/CEO reports to a 15-member International Board of Directors and regularly interacts with the Executive Committee of the Board. Under the direction of the President/CEO, the 50-member professional staff administers the programs, services and activities of the organization within a \$10-12 million annual operating budget. Of the 50 professional staff members, 47 are located in Tampa; three operate from home-based offices in the U.S. or Europe. The staff, under the direction of the President/CEO, supports the work of numerous organizational bodies, which may include:

- Board of Directors
- ISPE Strategic Forum
- Regulatory and Compliance Committee
- International Leadership Forum
- Three Regional Advisory Councils (comprising representatives of the Europe, North/South America, and Asia-Pacific affiliates)
- Board working groups focused on chapter collaboration and strategic direction
- Approximately 15 committees
- 19 Communities of Practice (CoPs) that offer interaction with colleagues in the various disciplines.

ISPE also sponsors approximately 40 chapters and affiliates located in the Asia-Pacific, Europe and North/South America regions; this structure offers the opportunity to network with industry professionals, meet with colleagues, attend events and participate in activities in specific geographic regions.

Key External Interactions

In addition to working closely with the International Board of Directors, staff and volunteer leaders, the President/CEO represents the organization's interests through interaction with a wide range of entities, including regulatory agencies; industry and academic leaders; and vendors, suppliers and manufacturers. These may include but are not limited to:

- Food and Drug Administration
- PMMI-The Association for Packaging and Processing Technologies
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- Parenteral Drug Association (PDA)
- American Association of Pharmaceutical Scientists

- World Health Organization
- International Leadership Forum
- European Medicines Agency
- Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme
- Biotechnology Industry Organization
- European Federation of Pharmaceutical Industries and Associations
- Rx360
- Engineering and Construction Contracting Association
- CASSS (formerly known as An International Separation Science Society)
- ASTM (formerly known as the American Society for Testing and Materials)
- Various other national regulatory authorities as circumstances warrant.

Strategic Organizational Focus

ISPE's planning efforts reflect the Society's commitment to leading members in shaping industry; engaging the pharmaceutical manufacturing community; and serving as a catalyst for contemporary solutions that influence global public health. These efforts focus on pharmaceutical development, manufacturing and quality of all medicinal and combination products, and on leading and defining excellence in:

- Leading dialogue and education that results in change in manufacturing
- Influencing regulatory harmonization
- Optimizing current manufacturing operations
- Developing next-generation manufacturing
- Creating and managing product supply networks
- Practicing enterprise risk management
- Shaping facilities of the future

ISPE is nearing completion of a three-year plan that has achieved visible results in the following key areas:

1. **Financial stability:** ISPE will experience year-over-year growth in gross and net revenue and build prudent reserves.
2. **Brand identity and leadership:** ISPE will be the leading society addressing scientific, technical and regulatory advancement and viewed by individuals, companies and regulators as the primary resource and partner in meeting their professional needs.
3. **Conferences and educational events:** ISPE will be a leading forum for practical and emerging information and preferred provider of education and knowledge for individuals and companies.

4. Members: ISPE will be increasingly known for efforts that meet information, education and networking needs of individual members and their companies.
5. Membership networks: ISPE will continue to distinguish itself from competitors by offering unique relationships through its chapters, affiliates, CoPs and special interest groups. These networks and forums will provide opportunities for advancing innovation generally and informing ISPE's future product development.
6. Regulatory affairs: ISPE will partner with regulatory agencies around the world to develop and be instrumental in leading consensus on industry issues; conducting education and training; and serving as the authoritative technical and scientific resource to regulators.
7. Systems: ISPE will operate with transparency and vision in governance, regulatory and knowledge development. Its underlying systems (technology, processes, Board and staff development) will be aligned to enable the delivery of value and drive organizational stability while achieving maximum return on members' invested time and resources. An effective communications action plan will be in place.

Programs, Services and Resources

Members give ISPE high marks for its extensive offering of programs, services and resources, particularly the ISPE-FDA Annual Conference, the ISPE Annual Meeting and ISPE/FDA co-sponsored events. ISPE is known for the outstanding content of its events; its extensive library of publications and technical guidance documents; networking opportunities; and online learning options. Key programs and services include the following:

1. Pharmaceutical Engineering magazine: The preeminent publication for the industry, the bi-monthly magazine features articles that provide practical application information, technical articles, case studies, global regulatory news, technology trends and new products.
2. Conferences and events: The ISPE Annual Meeting is the Society's premier event and includes more than 50 education sessions, training courses, networking events, exhibits and sponsorship opportunities. In 2014, ISPE will launch PharmaEXPO, a joint venture with PMMI that is envisioned to develop into a major international trade show and educational event and a significant revenue generator for both associations. Numerous other international and domestic events are held throughout the year and provide technical training and access to industry and regulatory resources.
3. On-site training: More than 60 two-day courses are designed and customized to meet members' specific needs and requirements, and are conducted at members' work sites.
4. Career resources: Job listings, information for emerging professionals, and free videos, webinars, articles and links help members maximize a job search.
5. Online learning: Live and on-demand webinars, webcasts and courses are available in a number of areas and disciplines.

6. Publications and resources: The extensive library of publications and resources includes:
 - a. Guidance documents on manufacturing best practices, regulatory compliance and international trends;
 - b. Knowledge briefs with concise resources on a variety of disciplines and topics;
 - c. E-letters, generated by ISPE's CoPs and delivered via email; and
 - d. Clinical trials and investigational products publications, to familiarize members with terms and related information they need to be successful in the field.

Recently ISPE has led global industry initiatives on drug shortages, quality metrics and breakthrough therapies that have elevated its visibility throughout the membership, regulators and healthcare authorities.

As is often the case with large and diverse organizations, members cited some areas in which they would like to see programs or services expanded or strengthened. These include alternate means of delivering educational programming in a more cost-effective manner; the increased use of web-based tools and social media to strengthen communication among members; marketing and delivery of industry products; and more timely delivery of technical guidance documents. It is a goal of the Society to enhance its level of resources and communications presented in multiple languages and adapted for local conditions appropriate for international members' needs.

Organizational Culture

The culture of ISPE is an important part of the value that the organization provides to its members and to the global community. The key principles expressed in ISPE's statement of value to members, staff and stakeholders include leadership, quality, collaboration, best practices, professionalism and inclusivity.

The ISPE staff has been engaged in a change management effort since 2012, when its 27-year President/CEO retired. This business and culture change effort initiated transition from an administratively focused staff to a more contemporary team responsible for business plan development and performance. A number of staff positions were upgraded to achieve this goal, and the development of a more innovative and accountable culture continues. A member-led and staff-driven business model is optimal.

Stakeholders understand that the association's many initiatives tax the time of its top staff talent, and that they would benefit from continued recruitment of executive leaders, further professional development and technological tools to help manage their businesses. Staff

members generally agree with this assessment, acknowledging that they are currently positioned more to implement programs and services than to develop them. The organization has done well in recruiting new staff and advisors with in-depth industry knowledge and association expertise. Continued staff development will be a key focus of the new President/CEO.

The ISPE member leadership is evolving in part to strategic repositioning of the Board and the current CEO's success in recruiting top executive talent to the Board. The diversity on the Board, which comprises members whose positions range from project management to executive leadership in multi-national companies, reflects the strengths and challenges of the Society's strategic position. A dichotomy exists in the members' view of the mission and purpose; the new leader must unite these constituents and develop value propositions that resonate with each segment. Generally, the volunteer leadership is described as passionate and dedicated to the mission of the Society. A new volunteer leadership program has recently been launched to support recruitment of new volunteer talent and develop the next generation of leaders and emerging professionals.

The membership generally respects the work of the Society and its resources and support for the profession. As is often the case in large and diverse organizations, the Society would benefit from greater engagement of the membership in all segments, and a more balanced "sharing of the workload of volunteerism" throughout the organization. Members are described as engaged at the local chapter and affiliate levels; vocal about their specific technical needs; and appreciative of opportunities at the local levels to share knowledge and take advantage of educational offerings, particularly in an environment of tightened budgets. Similarly, in the last two years, executives representing the industry and regulators are significantly more engaged in ISPE and view the Society as a leader and key influence in industry technical issues.

The local chapters and affiliates are described as "vibrant" by some stakeholders and as "insular" by others. They function largely independently and have been reasonably successful in meeting their respective members' needs; but they would welcome greater support and efforts to engage them by the national/international leadership.

Challenges and Opportunities

Stakeholders agree that the rapidly changing industry environment (particularly in terms of technology, regulatory requirements and business management approaches), financial pressures and changes in business models in the pharmaceutical and biotech communities

create a number of opportunities if the organization can move effectively and efficiently to take advantage of them. Internally, challenges include retaining members and attracting new members; creating a positive revenue-generating program and enhancing long-term financial stability; and strengthening the organizational infrastructure. Other challenges and opportunities include:

1. Institutionalizing a formal needs assessment/product development process as the basis for activities and resource allocation, including prioritizing the technical focus of the Society. The new Strategic Forum created in 2013 is expected to take on this task and is in the formative stages;
2. Heightening the awareness of and taking appropriate steps to create activities responsive to the diverse and unique cultures in the Society;
3. Strengthening and leveraging relationships with the chapters and affiliates to better engage and serve members;
4. Increasing the organization's relevance for regulators in an environment of fast-changing regulatory requirements;
5. Increasing the organization's agility in being able to consistently address emerging issues in a timely manner, and to compete more effectively to introduce product to market;
6. Maintaining engagement of industry leaders and regulatory authorities in order to enhance ISPE's position as the leading organization to achieve global harmony for scientific and technological practices;
7. Maintaining an effective presence and visibility in global markets;
8. Continuing the transformation of the Society into a more competitive and leaner business environment locally, domestically, and globally; and
9. Continued development of contemporary governance practices, norms and other behaviors reflective of a stable society; specifically continuing to move the Board and other leadership teams to strategic versus tactical agendas.

In addition, the Board has chartered a small, focused team of industry executives to develop a Strategy White Paper summarizing key strategic drivers that are both shaping the industry as a whole and that are expected to influence the strategic direction of the Society as a result. The Strategy White Paper is not intended to be directive, but rather informative to the new CEO.

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