

ENGINEERING PHARMACEUTICAL INNOVATION



ISPE OVERVIEW



Core Purpose

Developing innovative professionals globally to achieve technical and operational excellence in the Pharmaceutical Industry.

Vision Statement

The Society will lead the integration of Industry Professionals, Academia, and Regulatory Agencies worldwide to achieve real innovation and understanding in the pharmaceutical industry.

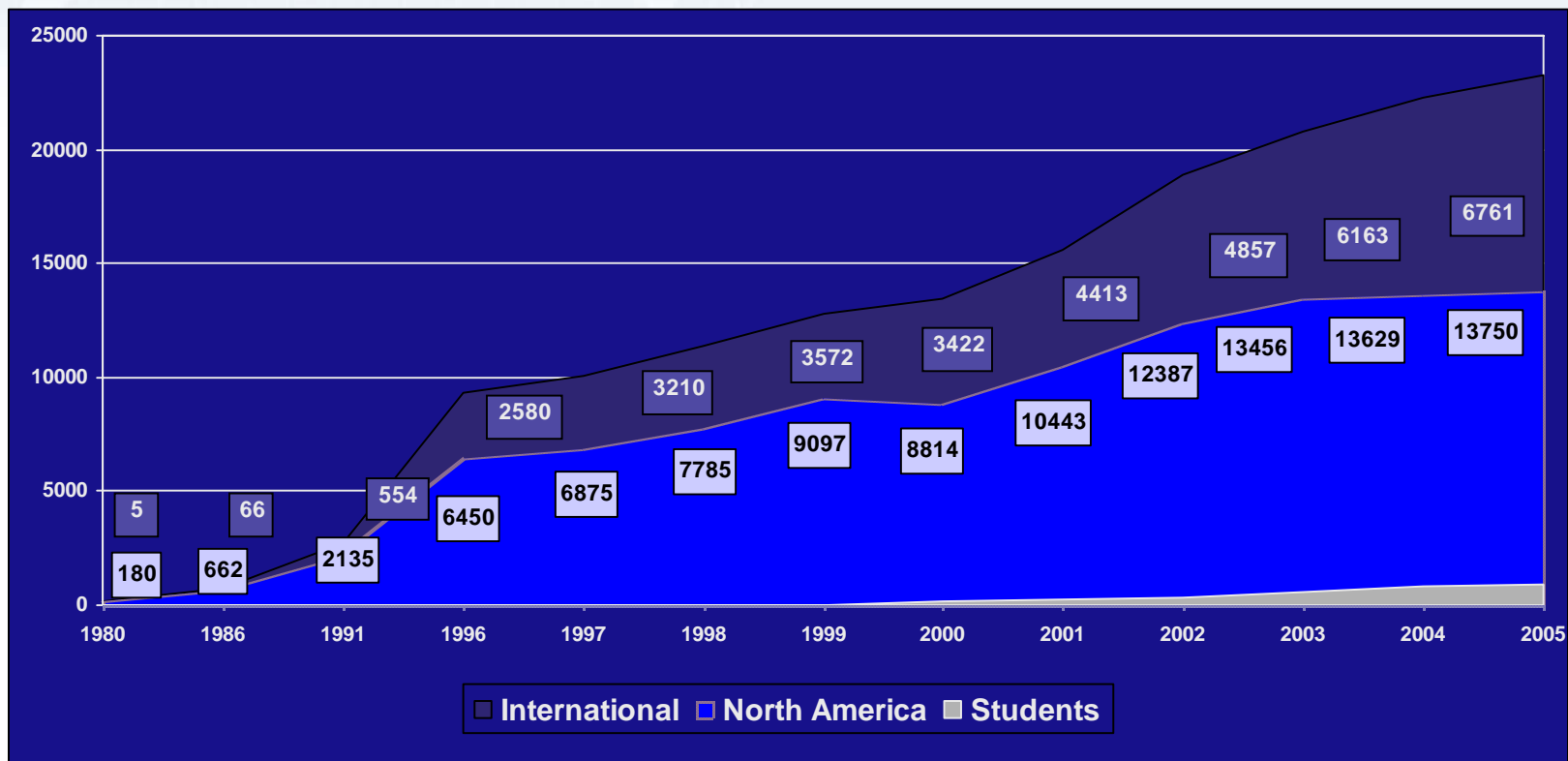
ISPE's Core Values

- Professional Excellence based on scientific and technical merit
- Practical Solutions achieved through open interaction among all facets of Industry, Government, and Academia
- A comfortable, caring, inclusive environment for individuals from diverse constituencies around the world
- Intellectual honesty and objective judgments based on integrity, trust, respect, and commitment
- Continuous improvement through sharing of best practices

ISPE Facts

- Founded in 1980
- Not-for-profit
- More than 23,000 Members in 81 countries
- Focused on education, information exchange, and technical documents for Industry
- Excellent relationship with regulators globally

ISPE Membership Growth



ISPE Membership Profile

- ISPE connects professionals from every aspect of the pharmaceutical industry in more than 81 countries. Our Members form a diverse group: industry professionals from manufacturing companies as well as suppliers, regulatory authority personnel of equipment and services, academia, and students.

ISPE Membership Profile

- Architecture / Engineering / Construction
- Clinical / Investigational Materials
- Health / Safety / Environmental
- Information Technology
- Logistics / Supply Chain Management
- Maintenance
- Operations / Manufacturing
- Process Control / Automation
- Process Development / Technology Transfer
- Project Management
- Quality Assurance / Control
- Regulatory Compliance
- Research and Development
- Sales / Marketing / Business Development
- Technical Services / Product Support
- Training

Organizations ISPE Members Work In...

- Academia
- Manufacturer / Operating
 - Traditional Pharmaceuticals
 - Biopharmaceuticals / Biotechnology
 - Contract
 - Generic
 - Veterinary Medicine
 - Medical Devices / Diagnostics
 - Bulk / API
 - Cosmetics
 - Food / Nutraceuticals
- Public Authority / Government
- Service Provider
 - Engineering / Architecture
 - Consulting
 - Validation / Qualification / Commissioning
 - CRO – Clinical or Contract Research
 - Construction Services Contractor
 - Facilities / Equipment Maintenance
 - IT / Computer Services
- Supplier
 - Equipment / Components
 - Packaging Materials
 - Clinical / Investigational Materials
 - Software / Hardware Products
 - Chemicals / Intermediates

Benefits of ISPE Membership

- Complimentary membership in an ISPE Affiliate/Chapter, affording local networking opportunities
- A subscription to the Members-only Pharmaceutical Engineering magazine, with access to on-line archives
- A Web-based membership directory with contact information for the more than 23,000 members from over 81 countries
- Entry to exclusive Members-only resources at www.ispe.org, including global regulatory news and technical articles
- A subscription to ISPE's E-letter series for the latest on industry, regulatory and Society news
- Opportunities to participate in ISPE committees, councils, task teams, and Communities of Practice
- Preferred Member rates on ISPE training programs and conference registration fees
- Significant discounts on technical guides and other publications
- Complimentary services in our on-line Global Career Center

ISPE Web site, www.ispe.org

- On-line Membership Directory
- Search and download *Pharmaceutical Engineering* articles
- Technical Regulatory Information
- Regulatory News
- Listserv e-Discussions
- Global Career Center
- Global Event Calendar
- Reference Documents
- Glossary of Pharmaceutical Terms
- Global Supplier's Directory



ENGINEERING PHARMACEUTICAL INNOVATION

COMMUNITIES OF PRACTICE

AFFILIATES AND CHAPTERS

CAREER CENTER

REGULATORY RESOURCES

PUBLICATIONS

EDUCATION AND TRAINING

STUDENT RESOURCES

MEMBER BENEFITS

JOIN ISPE

ISPE Members

Looking? Search Here:

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What Our Members Say

ISPE's active commitment to its Members is clearly indicated by its excellent track of organizing seminars and conferences, as well as trainings and classes.... Kudos to ISPE for a continuous excellent



ISPE is the world's largest not-for-profit professional society serving pharmaceutical manufacturing professionals. As a Member of ISPE you join experts around the globe in sharpening your skills, building a career, defining best practices and interacting with regulators. Explore our site to see how we can benefit you.

Quick Start Please Select...

Advertise, Exhibit, Sponsor Media

Industry and Regulatory News ISPE Update

- FDA announces establishment of the Office of New Drug Quality Assessment (ONDQA) effective 1 Nov 2005.
- Lester Crawford Resigns Unexpectedly as Commissioner of FDA. President Bush names Andrew C. von Eschenbach, M.D Acting Commissioner.
- Encouraged by FDA, ISPE Releases RABS Definition Paper.
- FDA Issues Final Risk Minimization Guidances
- New Improvements in FDA's Drug Safety Monitoring Announced
- ACME Expands Global Outreach with New Asia Pacific Office

MORE NEWS

MORE UPDATES

Logon My Account

Shape the Future

Get Involved with Communities of Practice and cutting edge committees.

MORE

Invest in Learning

Education, Training, Certification, and On-line Seminars to boost your career.

MORE

Leverage Resources

Publications, Glossary, Suppliers Directory. Explore what matters.

MORE

New to the Industry?

Top twenty steps to get a jump start on the profession.

MORE

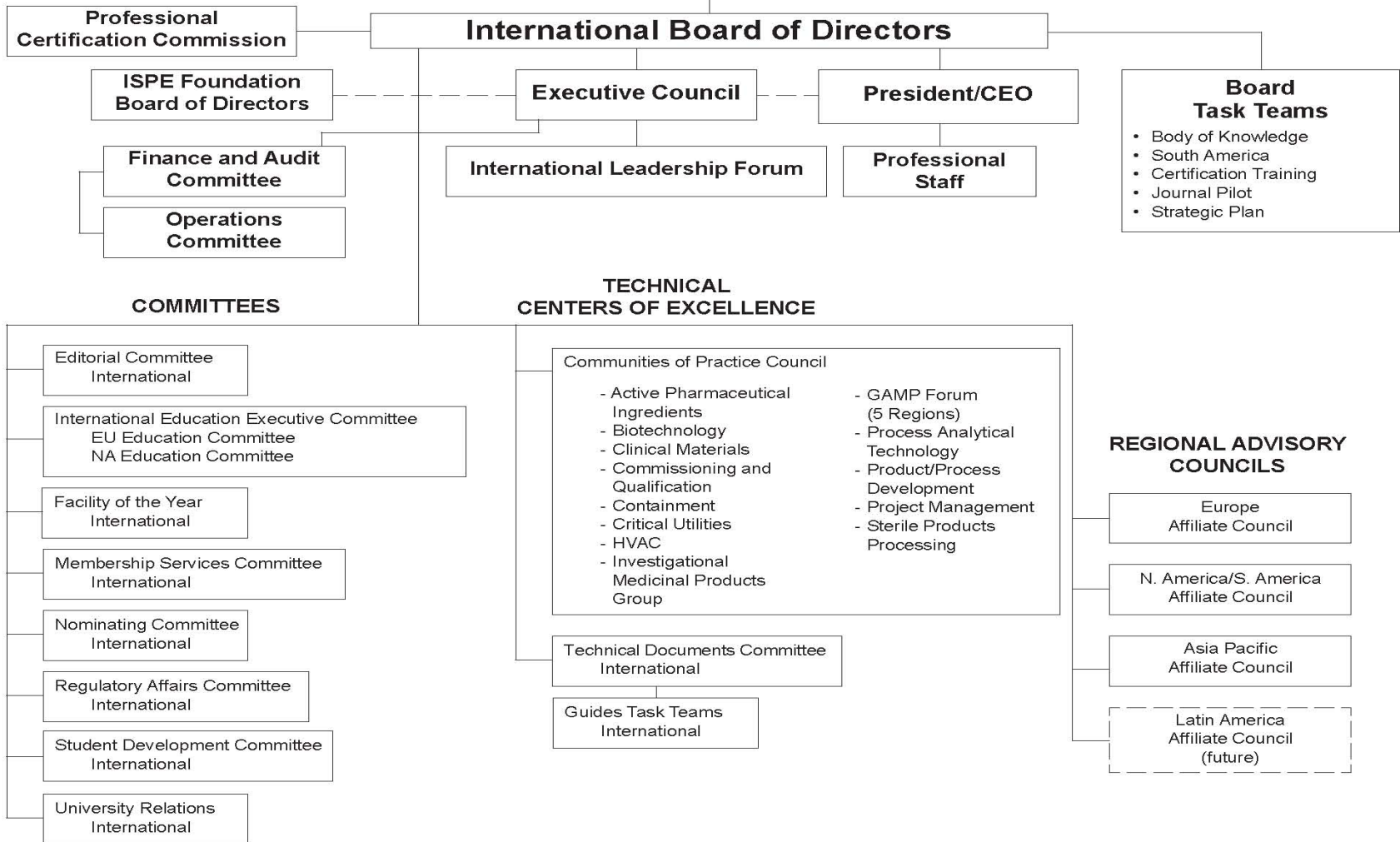
ISPE Online Tour

First time here? Or a regular member wanting to take advantage of more of what ACME offers?

Start with a tour of our virtual global



THE MEMBERSHIP



ISPE Chapters and Affiliates

- Chapters are
- Affiliates are

ISPE Affiliates

- Organized and run by local ISPE Members
- Provides a forum for transfer of industry/regulatory information and technology on a local basis
- Provides access to:
 - Educational seminar/training programs
 - Industry/regulatory/academia/professional networking
 - Facility tours
- Develops a Web site in native language

ISPE Affiliates Worldwide

- Asia Pacific Affiliates
 - Australasia:
 - Brisbane Chapter
 - Melbourne Chapter
 - New Zealand Chapter
 - Sydney Chapter
 - India
 - Japan
 - Singapore
 - Thailand

ISPE Affiliates Worldwide

- European Affiliates
 - Belgium
 - Czech Republic/
Slovakia
 - France
 - Germany/Austria/
Switzerland
 - Ireland
 - Italy
 - The Netherlands
 - Turkey
 - Nordic
 - Poland
 - United Kingdom:
 - Central Region
 - Northeast Region
 - Northwest Region
 - Scotland Region
 - Southern Region

ISPE Affiliates Worldwide

- North American Affiliates
 - Canada Affiliate
 - Central Canada Chapter
 - United States Affiliate
 - Boston Area Chapter
 - Carolina-South Atlantic Chapter
 - Chesapeake Bay Area Chapter
 - Delaware Valley Chapter
 - Great Lakes Chapter
 - Greater Los Angeles Area Chapter
 - Midwest Chapter
 - New England Chapter
 - New Jersey Chapter
 - Pacific Northwest Chapter
 - Puerto Rico Chapter
 - Rocky Mountain Chapter
 - San Diego Chapter
 - San Francisco/Bay Area Chapter
 - South Central Chapter
- South American Affiliates
 - Argentina Affiliate
 - Brazil Affiliate

ISPE Affiliates

88% of ISPE Members
belong to an Affiliate or
one of its Chapters

ISPE's Education Program

For the technical professional



For the business entity

Body of Knowledge

- Business Operations
- Development and Manufacturing Technology
- Facilities and Engineering
- Regulatory / Compliance / Quality

Education

- Conferences – hot industry topics and networking to share ideas and discuss global issues
- On-line Seminars – industry developments at your desktop
- On-site Training – solutions to your company's specific training needs
- Classroom Training – to further your career and apply best practices

ISPE Industry Guidance

- ISPE began with the Baseline® Guides
- Since then, ISPE created GAMP, GAMP Good Practice Guides, and ISPE Good Practice Guides like Technology Transfer
- Now providing technical input to Regulatory Agencies such as FDA, EMEA, JMHLW, WHO, ICH
- Developed E-Learning and classroom courses to train investigators

The ISPE logo, tagline, GAMP, and Baseline are registered trademarks of ISPE.

ENGINEERING PHARMACEUTICAL INNOVATION





- **Currently Available**

- Bulk Pharmaceutical Chemicals
- Oral Solid Dosage Forms (in revision)
- Sterile Manufacturing Facilities (2007)
- Water and Steam Systems
- Commissioning and Qualification
- Biopharmaceutical Manufacturing Facilities

- **Upcoming Guides**

- Packaging, Labeling, and Warehousing Operations (2006 Q4)
- Maintenance (2007)
- Laboratories (2007)



Professional Certification Commission

- Formed to govern professional certification programs
- Maintains autonomy and administrative independence from the ISPE Board of Directors regarding credentialing decisions
- Composed of 14 Commissioners representing; Australia, Japan, The Netherlands, North America, United Kingdom

Professional Certification Commission

The Mission:

To serve the global pharmaceutical and biotechnology industry by establishing competency standards for drug product development and manufacturing professionals.

To elevate the status of industry professionals, provide employers with competent workers, facilitate development and manufacturing innovation, and enhance drug product quality.

Professional Certification

A new international credential for the global pharmaceutical industry

The Credential:

Certified Pharmaceutical Industry Professional (CPIP)

“Fostering innovation through demonstrated knowledge diversity”

The Professionals:

Individuals from academia, industry, and government engaged in or supporting the development and/or manufacture of drug substances, drug products, or drug delivery systems



Professional Certification

- CPIP Credential Applicants:
 - Open to anyone in the world meeting eligibility criteria
- CPIP Eligibility Criteria:
 - Science/engineering/technical/math degree + 5 years of industry-related experience
 - Non-science/engineering/technical/math degree + 10 years of industry related experience
- CPIP Written Examination:
 - Required after eligibility acceptance
 - Credential awarded upon passing examination

Professional Certification

- **CPIP Credential Schedule:**
 - International job analysis – February '06
 - Examination development – March '06 to March '07
 - Applications available – November '06
 - Study Guide available – November '06
 - 1st examination planned – June '07

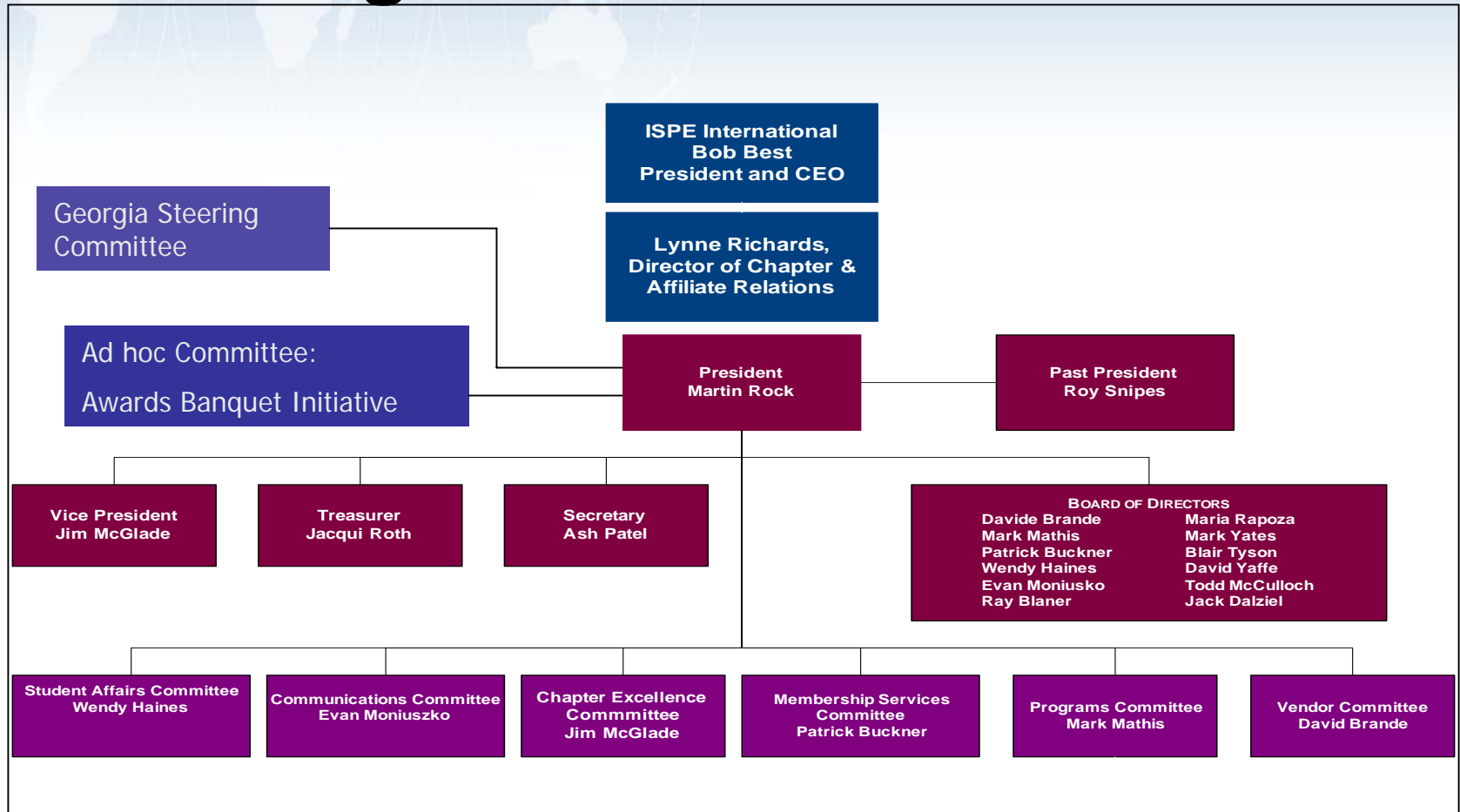
ISPE CASA Chapter Overview

- Founded in 1991 by Pat Lewis, GSK
- Originally called Carolinas chapter, added GA, SC, AL, FL and TN after 2000
- 1200+ members
- 3rd largest behind NJ and Delaware Valley
- Five Chapter Excellence Awards
- Chapter Website www.ispe.org/carolina-southatlantic.com

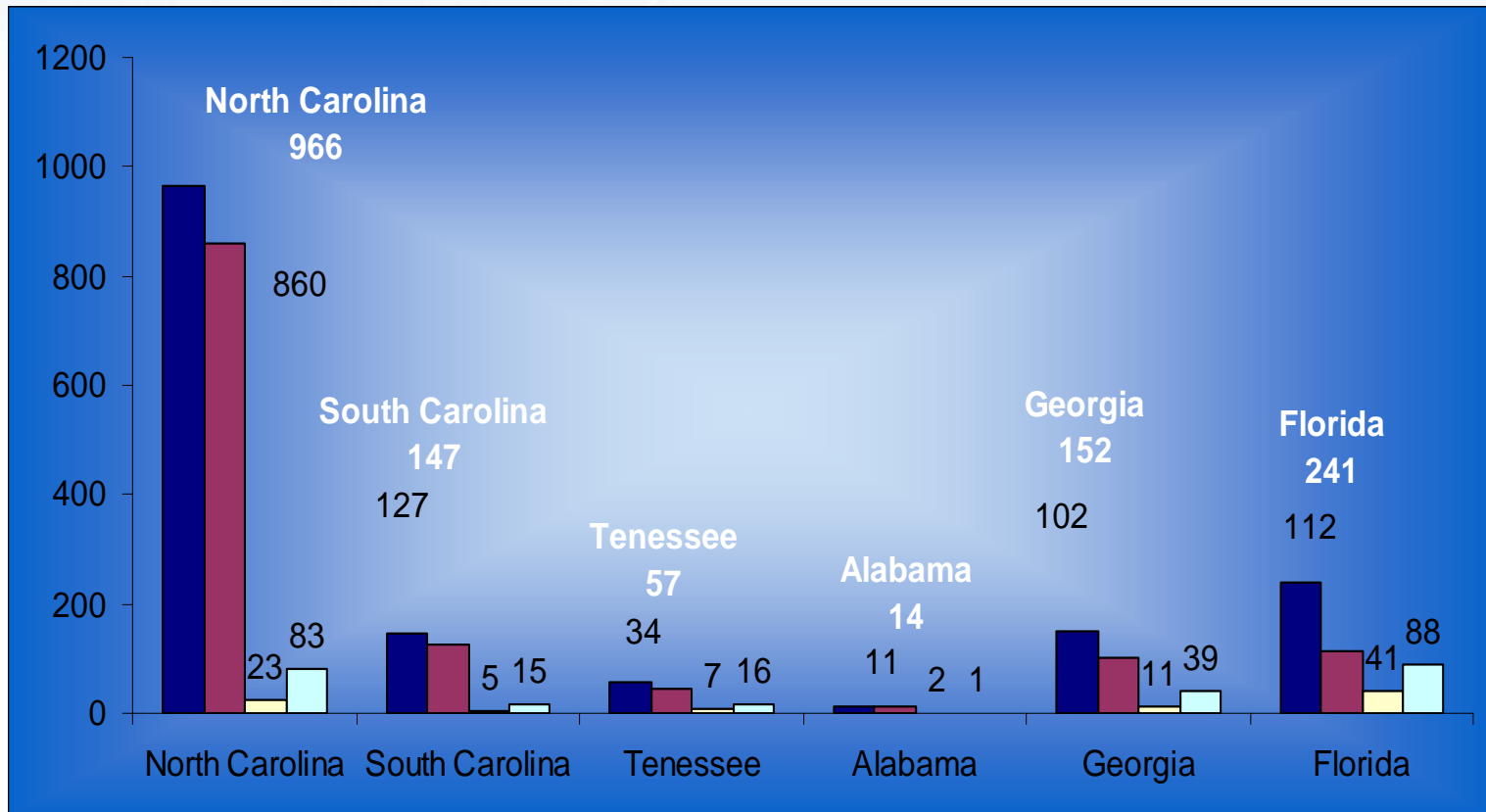
CASA MISSION

To provide high quality local educational programs, social events, and other services to our membership in support of the core purposes and goals of ISPE.

CASA Organization Structure



CASA Demographics ~ 2004



CASA Student Chapters

- **Campbell University**
- **Clemson University**
- **James Madison University**
- **North Carolina State University**
- **North Carolina A & T State University**
- **University of North Carolina**

Chapter Manager

- **Administrative Duties:** Manage administrative duties of the Chapter
- **Financial Responsibilities:**
Assist the Treasurer with the financial operations
- **Communications:** Coordinate and distribute internal and external communications and assist in the publication of Chapter publications.
- **Leadership Support:** Support the leadership in strategic planning, leadership training and orientation, budget planning and monitoring, and developing policies and procedures.
- **Meeting Management:** Assist the committee chair for any planned meetings.
- **Executive Staff:** Debora Steenson provides leadership for the ISPE-CASA management team at Management Concepts, Inc. Debora was recently named as Vice President of the nationally recognized firm and leads the MCI team as well.
- **Executive Management:** MCI has received credentialing from the American Society of Association Executives in Washington, D.C., representing one of 50 in the nation to receive this prestigious honor. This assures ISPE-CASA quality in professional management services.

ISPE-CASA@mgmt4u.com; 919-861-1123.