



Helping Clients De-Risk Biopharmaceutical Development Since 1994

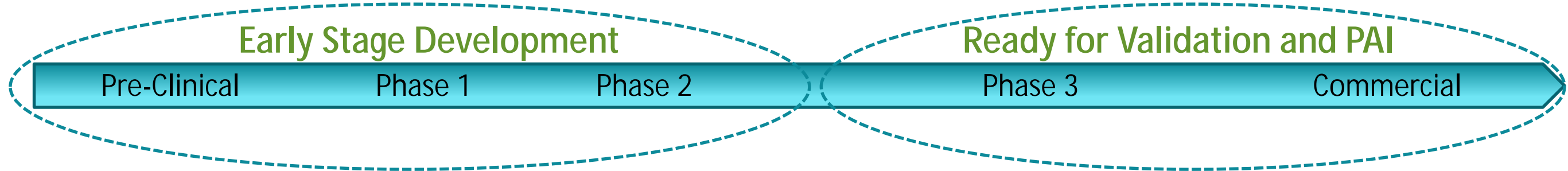
BioProcess Technology Consultants, Inc.
www.bptc.com

Who We Are



- ∅ The biopharmaceutical development experts
 - Over 20 results-oriented professionals assisting clients since 1994 to advance and de-risk the biopharmaceutical development process, address unmet medical needs and increase patient access to novel medicines
 - A team of subject matter experts with real world experience who deliver cutting-edge, solution-oriented consulting services directed specifically to client needs and mission

Resources, Expert Advice, and Guidance Throughout Development



Process and Analytical Development

- Optimal Cell Line Development
- Phase-appropriate Process Development
- Develop, Qualify, and Validate Analytical Methods
- Validation Planning and Support

advanceONE® Quality and Regulatory Services

- CMC Regulatory Strategy and Requirements
- Design, Implement and Manage Quality Systems
- Compliance Audits
- Preparation of Global Regulatory Submissions

Manufacturing Strategy and Operations

- "Make vs. Buy" Manufacturing Options
- Project Management and Communications
- Facility Conceptual Design and Validation
- Identify and Manage Service Providers



Business Services to Support Strategic Initiatives

- Where is the capacity? Who is investing?
- Product pipeline tracking
- Fit complex and unique products to CDMO experience

- Support mergers and acquisitions
- Critically review CMC status and probability of regulatory success
- Define critical steps and activities for product advancement



- Estimate manufacturing costs
- Evaluate economic impact of new technologies or process changes
- Assess relative costs manufacturing options

- Identify market opportunities and needs
- Competitive intelligence and market research
- Evaluate technology trends

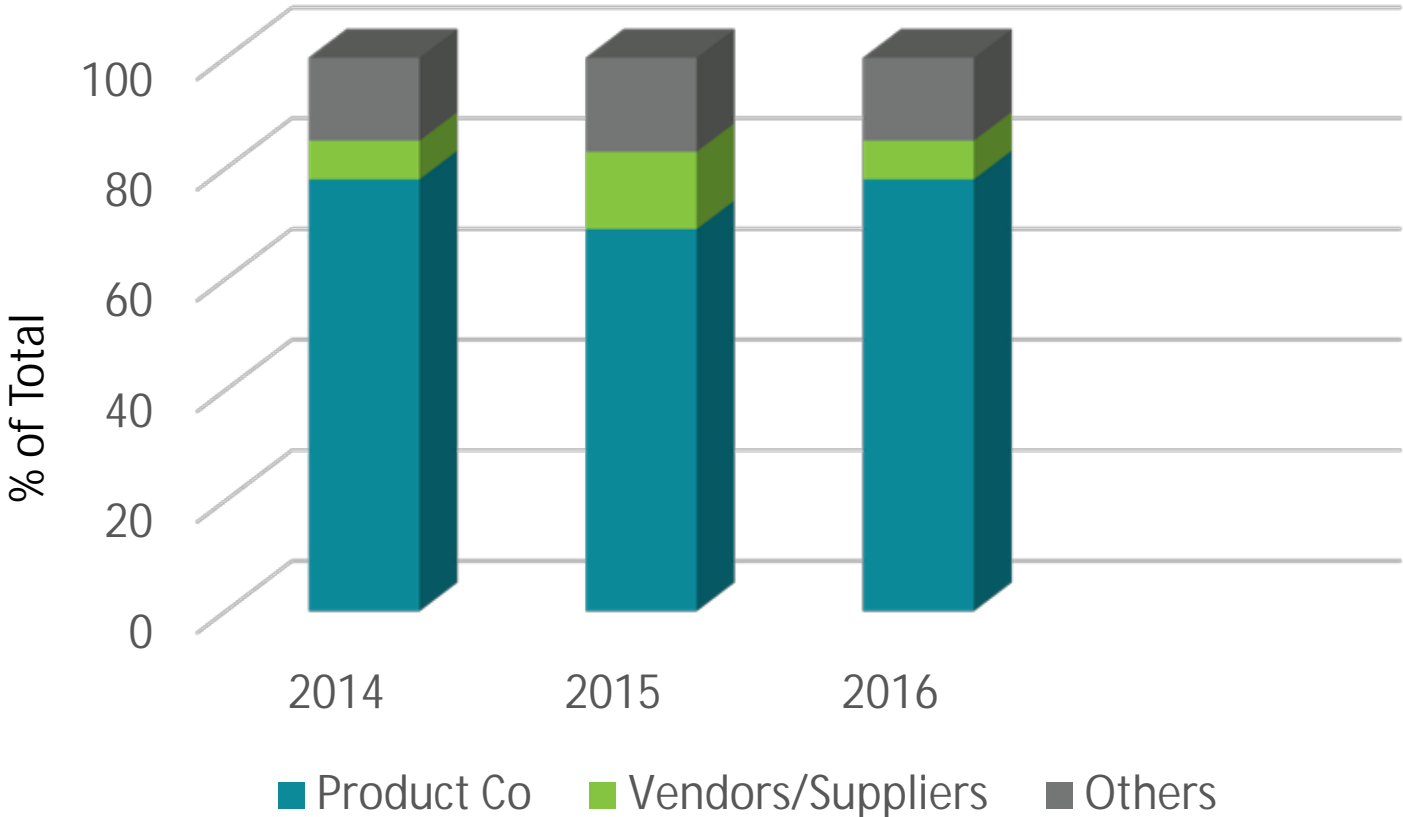
Our Clients and Services

- Over 1,000 consulting projects since 2000 for companies ranging from small virtual biotech companies to large pharmaceutical companies, investors, and suppliers
- 50% of BPTC client projects include QA and/or QC support, including the preparation and management of quality management systems
- Participated in over 100 global regulatory submissions over the past five years

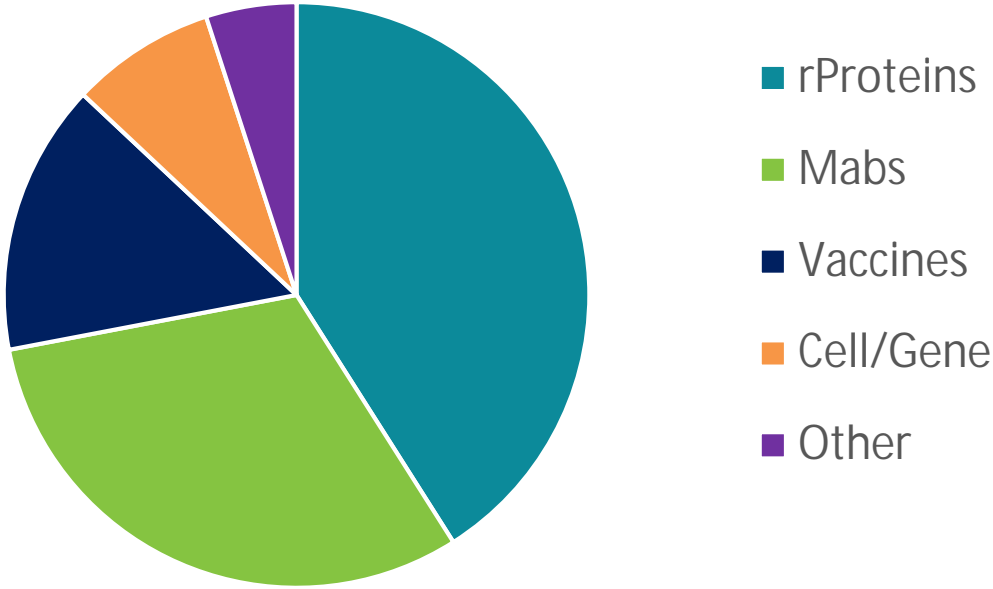


Client/Project Demographics

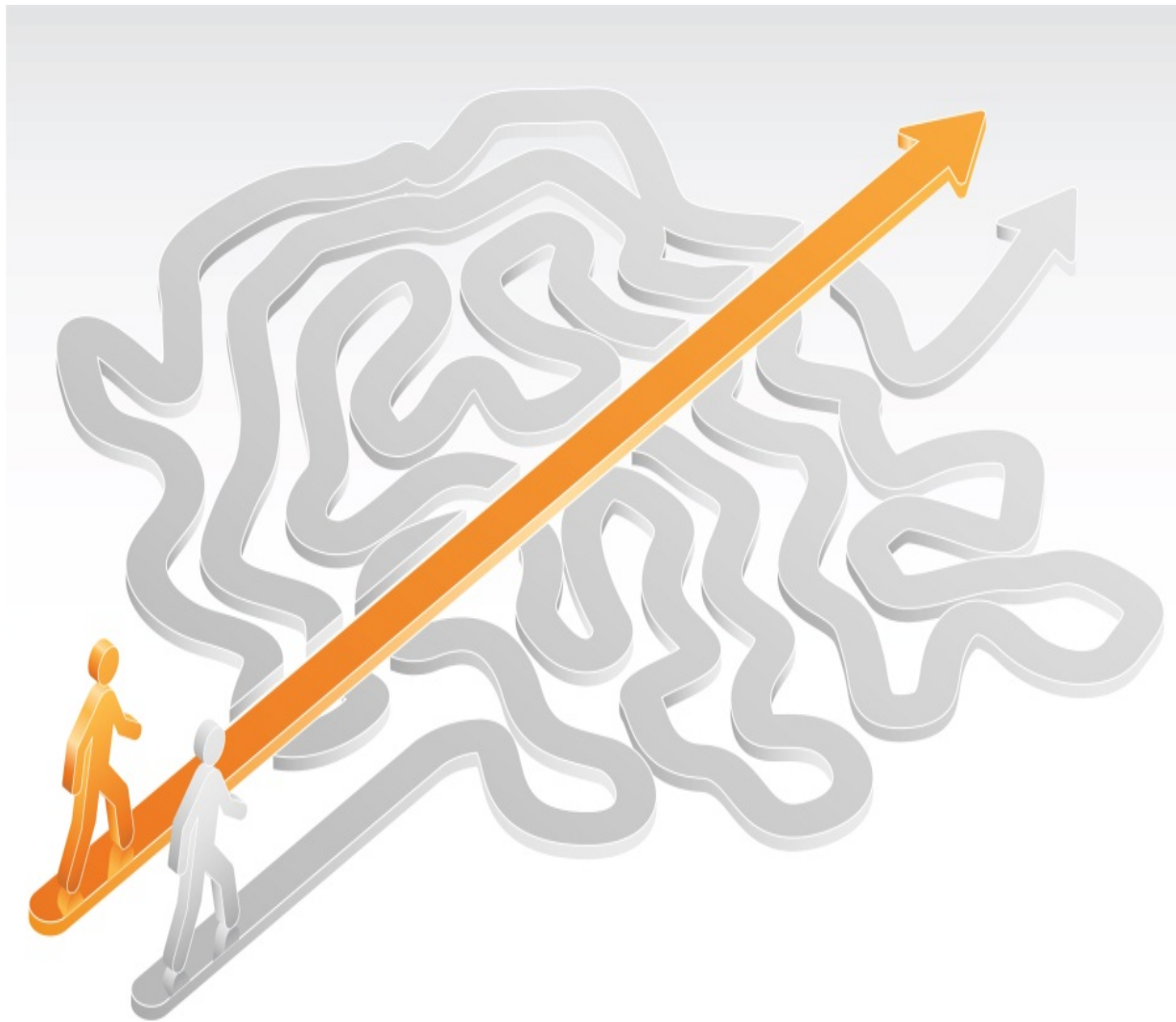
Distribution of Projects by Client Type



Distribution of Products Supported in Five Year Period 2011 – 2016



BPTC: The Clear Path to Success



- ∅ Making the right choices for
 - Product development path to IND filing and commercialization
 - Transitioning from clinical development to PAI success and a commercial product
- ∅ A team with unparalleled knowledge and experience of biopharmaceutical development, manufacture and supply services
- ∅ Committed to staying at the forefront of knowledge
- ∅ Providing straightforward guidance through a complex technical and regulatory environment



Thank You!

For more information contact:

Al Doig

p: +1.781.281.1869 | m: 1+.781.640.0627 | email: adoig@bptc.com

BioProcess Technology Consultants, Inc.

12 Gill Street, Suite 5450

Woburn, MA 01801