

Scientific Process Organization

Creating value with in-depth scientific knowledge, insights, processes and technology

Industry Trends and Challenges

Drug development is a highly regulated process that is becoming increasingly complex. In order to succeed and remain competitive in this challenging environment, biopharmaceutical, consumer and medical device companies must stay on top of the ever changing product lifecycle landscape such as clinical development processes and procedures, global health authority regulations and guidelines, and rigorous post-marketing requirements to name a few. Managing the spiralling process complexity and product development economies, all while maintaining high quality standards demands a smarter and bolder approach.

Organizations are increasingly looking to partner with specialized knowledge service providers to derive efficiency, expertise, scale and cost benefit.

Organizations partner with SPOs for high-end science-based activities to derive value from access to a highly skilled and talented workforce and for improved quality outcomes, operational efficiencies and cost optimization. In today's competitive environment, organizations must focus on their core competencies and outsource non-core activities in order to achieve their objective to deliver high quality products. By outsourcing these activities, not only are efficiencies improved and costs optimized, but the total business also improves because the focus of the internal experts shifts to the key growth areas of the organization.

A New Category of Outsourcing Vendors is Emerging to Meet Unmet Needs

The advent of Scientific Process Organizations (SPOs) is due to the increasing demand for a higher level of scientific expertise that is normally not catered by traditional Business Process Organizations (BPOs) or Contract Research Organizations (CROs). SPOs are dedicated to filling the gaps left by these other companies who may focus more on operations than science, or more on science and less on process, or larger multi-industry organizations that lack specialization in Life Science.

SPOs attract a pool of talent with diverse scientific capabilities and incorporate a business model that is designed to meet the needs of all their clients. With deep subject matter expertise in all phases of drug development, from initiation of clinical trials to post-marketing support, SPOs are able to tailor a flexible solution to help their clients quickly and efficiently bring drugs to the market and manage their product lifecycle in a compliant manner.

Sciformix Corporation (Fig 2) is an example of a SPO. Their strength in the area of safety and risk management, a process that is rapidly increasing in both importance and complexity, ensures the best possible outcomes for patients and manufacturers with regard to product safety. In addition, their expertise in clinical development and post-approval support is expanding and evolving to meet the constant barrage of global market and regulatory demands, while ensuring that patient safety and product efficacy outcomes are met with high quality.

What is a SPO?

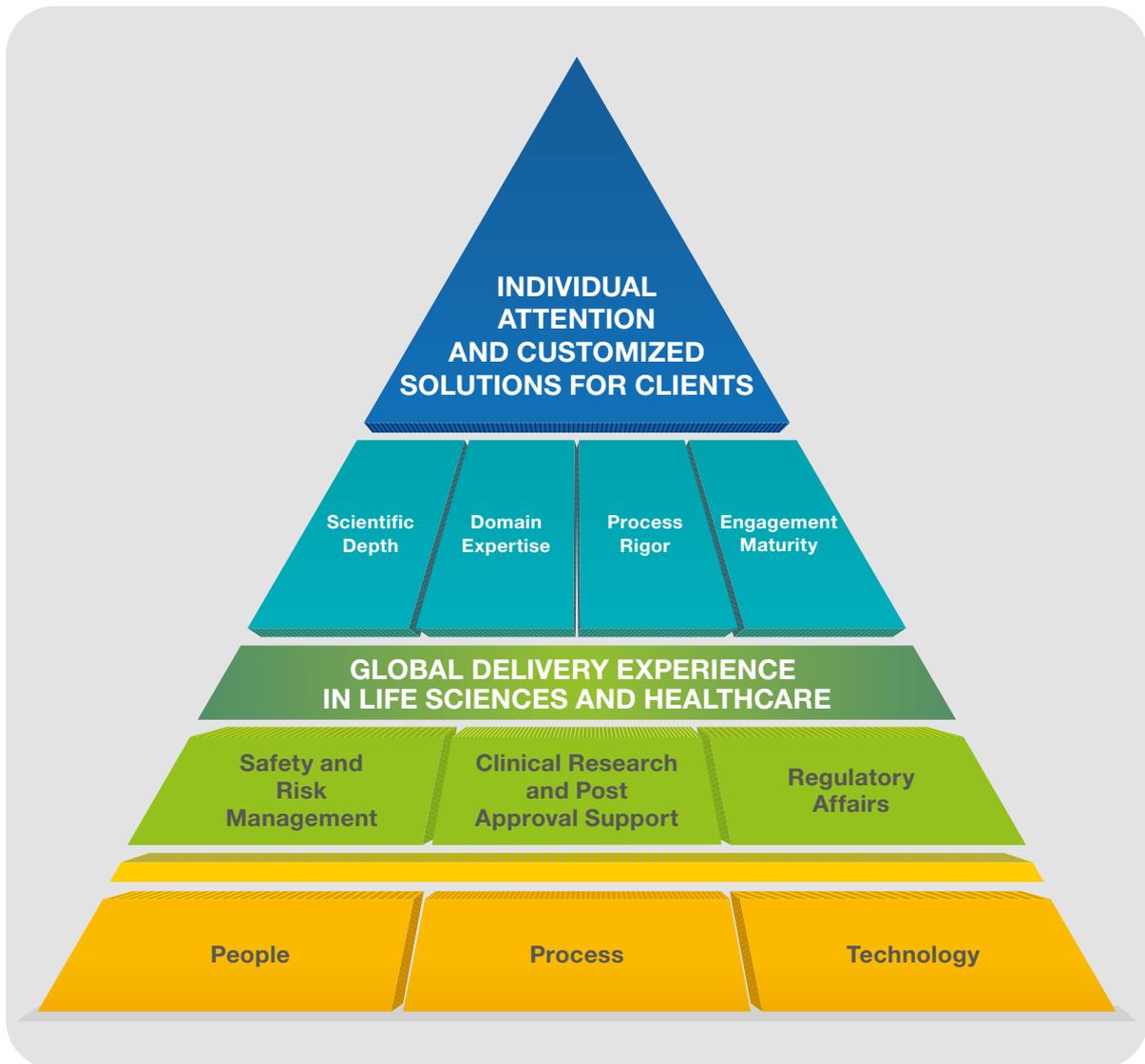
Scientific processes or science-based processes can be defined as domain-intensive processes in a scientific area where the outcome is highly dependent on the subject matter knowledge and experience of the people carrying out the activity. SPOs create value for their clients through their singular industry focus, strong domain competency, exceptional subject matter expertise, uncompromising focus on quality, streamlined processes and technology innovation. This unique platform ensures consistent, predictable and high quality results and affords SPOs the flexibility to scale and provide customized solutions for their clients (Fig 1). Some examples of how SPOs create unique value-added benefits are detailed in the next two sections.

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FIG 1 - SCIENTIFIC PROCESS ORGANIZATION



More Informed Decisions

The evolving global regulatory environment has resulted in a significant increase in the proactive analysis of product benefit and risk. Drug and product developers need to collect new types of data as well as analyze and report this data in different ways. The result is that organizations must rethink their overall approach to safety and risk management and how they manage aggregate reporting and safety writing. Employing dedicated staff with the right skill-set, knowledge and training - with supporting processes, tools and technologies - offers companies the ability to analyze their data more effectively. Life science specialists in data management, statistics and programming ensure fit-for-purpose analysis; while subject matter experts in therapeutic areas, regulatory affairs and scientific writing provide better insight and facilitate more informed decisions that are critical to maintain a products success.

More Efficient and Higher Quality Deliverables

The growing complexities in drug and product development have necessitated the need to streamline and integrate various processes. While best practices for Six Sigma and LEAN manufacturing are mature in many industries they are not transferrable to the unique workflows of the Life Science industry. SPOs know how to continuously implement specialized improvements that benefit clients. Sciformix LEAN projects are an integral element of our partnerships and focus on eliminating and automating manual or non-value-added steps in existing processes. Six Sigma projects aim to curb variations in processes and yield reduction in errors, thereby optimizing resource utilization and increasing overall quality.

FIG 2 - SCIFORMIX SERVICES

Preclinical	Phase 1	Phase 2	Phase 3	Post Approval
Safety & Risk Management				
Pharmacovigilance				
Aggregate Reporting				
Signal Detection & Risk Management				
Clinical Research & Post Approval Support				
Data Management				
Statistics & Programming				
Clinical Operations Support				
Clinical Writing				
Market and Competitive Intelligence				
Medical Information & Communication Support				
Regulatory Affairs				
Regulatory Strategy & Consulting				
Global Regulatory Submissions				
Regulatory Writing				
Global Product Labeling Management				

Sciformix Corporation is a leading Scientific Process Organization (SPO), providing science-based services to biopharmaceutical, generic pharmaceutical, consumer products, medical devices and other healthcare companies. Our mission is to partner with global life science companies to provide high quality scientific expertise that delivers better quality outcomes and improved efficiencies across the entire product lifecycle with the ultimate objective of improving quality of healthcare for patients worldwide. Key scientific areas of collaboration and partnership include safety and risk management, clinical development strategy, post approval support, medical affairs, regulatory affairs and scientific writing.

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