C-Level Fractionals

FSA can fill critical positions in the management team of start-ups and early stage life science companies. In addition to our skill sets and credentials, we can mentor the entrepreneur Founders and Managers as they build the company.

Benefits

• Experienced, credentialed leaders without long-term commitment and overhead costs.
• Focused and efficient problem solving. CLF's are able to quickly identify organization and growth inhibiting issues and recommend and install effective solutions.
• Lack of bias. Because CLF's are temporary and allegiant only to moving the business forward, they offer a clear perspective to the sr. management team.
• Scalable to the stage of the business.
• Provide confidence to investors, partners and collaborators. The appropriate CLF's in a management team significantly enhance the organization's ability to deliver on its commitments and reach its growth targets.

Roles / Positions

Chief Business Officer
Sr. Business Development Sr. Corporate Development
The scope of activities depend on the type of product/service and stage of development. For a biotech company with a preclinical or early phase asset, the position may be focused on finding collaborators and licensee's of the candidate or platform. For a CDMO, it would be bringing qualified clients into the facility and closing them. For a bioproduct company it could range from adding customers to setting up distribution channels.

In general, the responsibilities could include:
• Development of business opportunities
  - Sales Planning, sales force development & management, sales channel development.
    Outreach to prospects and buyers of the company's services and products.
    Direct sales to prospective customers/clients.
  - Product and Market development. Pricing strategies. Portfolio rationalization

• Corporate Development
  - Securing investment.
  - Licensing.
  - Alliance formation. Establish and coordinate collaborations.
  - Strategic planning

The CBO CLF is a highly credentialed senior manager who interacts and engages with counterparts in the life science community. They represent the company to stakeholders, clients, and investors. Within a defined scope of work, as a business professional, the CBO CLF is capable of effectively furthering the company's interests.

Chief Operating Officer (COO)
With oversight of the day-to-day operations of the company, this position can cover a range of responsibilities. At one end of the spectrum, co-leading the management team with the President/CEO. At the other, managing production related activities as part of a management team comprised of the President, CFO, and CBO.

In general, the Chief Operating Officer (COO) is responsible for overseeing the company's operational strategies, ensuring efficient processes, and driving business growth in the life sciences sector. This role requires a strong leader with deep industry knowledge to optimize organizational performance, manage key partnerships, and ensure compliance with regulatory requirements.

Key responsibilities could include:
• Management / Oversight of production.
Prior to the production stage, the COO would have a significant level of involvement in product/service development activities.
• Operational Leadership
Development and implementation of operational strategies to enhance efficiency and scalability in research, development, and commercialization.
• Regulatory Compliance
Ensuring adherence to industry regulations, quality standards, and best practices within life sciences (e.g., FDA, EMA, ISO, GMP).
• Financial Oversight
Management of budgets, resource allocation, and contribution to financial planning toward sustainability and profitability.
• Process Optimization
Lead continuous improvement initiatives to enhance operational efficiency and streamline workflows.
• Risk Management
Development of risk mitigation strategies to address potential operational, financial, and regulatory challenges.
• Technology and Innovation
Implementation of new technologies to enhance operational capabilities.

Associated responsibilities as needed in strategic planning, business development, stakeholder engagement.

Chief Financial Officer (CFO)

For start-up or early stage business, the CFO has two major responsibilities:
1. Setting up the accounting system.
Bringing on-line the appropriately compliant accounting system for the stage of the business and inputting financial data to provide usable information for sr. management, stakeholders, and regulatory authorities.
2. Providing leadership, credential, and confidence in financing activities.
By their actions, knowledge, and credential, the CFO takes a lead position in securing investment and establishing the banking relationships of the company. They de-risk the company to potential stakeholders in the financial community and act as a key liaison with investors, board members, auditors, and external financial partners.

As a key member of the management team the CFO is responsible for overseeing the financial strategy, planning, and operations of the organization. The CFO works closely with the executive team to align financial strategies with business objectives and to support sustainable growth. The CFO handles the financial reporting for the business. The CFO

The responsibilities of the CFO depend on the stage of the business. At the outset, the role is essentially Bookkeeper, Business Strategist, and Fund-Raiser. As the business grows/matures, the role evolves to include the activities listed here:

- Financial Strategy & Planning
- Budgeting & Forecasting
- Regulatory Compliance
- Capital Structure Formation & Management
- Alliance/Collaboration Financial Due Diligence
    - M&A at later stage
- Risk Management
- Cost Optimization

Purchasing / Supply Chain Management

Typically a single role in an early stage business. It may be combined with other functions to better justify the expense; E.g. Lab Manager, Accounting, IT. As the business grows this function becomes more important, frequently having a material effect on cashflow (burn rate) and/profitability.

Key responsibilities include:
- Establishment of the Procurement System including generation of SOP's and associated documentation
- Procurement & Vendor Management
- Inventory Management / Supplies Management
- Regulatory Compliance
- Logistics & Distribution
- Cost Control / Budget Management

Project Management

Overall, the Project Manager in Life Sciences is responsible for planning, coordinating, and executing projects related to research, development, regulatory compliance, and commercialization. Experience in managing complex projects, cross-functional teams, and stakeholders in a fast-paced, highly regulated environment is mandatory. The Project Manager will ensure projects are delivered on time, within scope, and budget while maintaining quality and compliance standards.

While effective Project Management is important in every type of Life Science business, it is particularly critical in contracted services and biomedical product development. In those areas, there is a direct connection to bottom line performance that is recognizable in the short and medium term. FSA has special expertise and a strong track record in managing project and programs for profitability.

Key responsibilities include:

• Project Planning & Execution
Development of detailed project plans, timelines, and milestones, ensuring alignment with business objectives.
• Cross-Functional Coordination
Collaboration with R&D, regulatory, manufacturing, quality, and commercial teams.
• Regulatory & Compliance Oversight
Ensuring project activities comply with regulatory requirements (e.g., FDA, EMA, GMP, ISO).
• Risk Management: Identification of project risks, development of mitigation strategies, and implementation of contingency plans.
• Budget & Resource Management
Monitoring and reporting on project budgets, allocating resources effectively, and ensuring cost efficiency.
• Stakeholder Communication
Liaison between internal and external stakeholders, providing regular updates on project progress.
• Process Improvement
Identification of opportunities to optimize project workflows, enhance efficiency, and ensure best practices in project management.
• Data Analysis & Reporting
Tracking key performance indicators (KPIs) and generating reports for executive leadership and stakeholders.
• Technology & Tools
Utilize project management software (e.g., MS Project, Jira, Smartsheet) to track and manage project timelines and deliverables.