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THE HUMAN FACTOR IN MODERN BIOTECHNOLOGY START-UPS: WHY EXPERIENCED DRUG DEVELOPMENT PROFESSIONALS SHOULD BE CONSIDERED AS IMPORTANT AS THE SCIENCE ITSELF

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ABSTRACT

The traditional perception that scientific innovation alone determines the success of biotechnology start-ups is increasingly challenged by the growing complexity of modern drug development. While breakthrough science remains essential, the ability to efficiently transform a scientific concept into a clinically and regulatorily credible asset has become equally—if not more—dependent on the experience and execution capabilities of the development team.

In today's life science ecosystem, many start-ups are built around licensing-out strategies typically occurring after Phase 1 or Phase 2 clinical development. Under this model, company valuation is strongly influenced by risk reduction, development speed, regulatory credibility, and operational execution rather than solely by scientific novelty. Simultaneously, advances in pharmaceutical technologies, biologics, analytical characterization, chemistry manufacturing and controls (CMC), and increasingly stringent global regulatory expectations have dramatically increased the complexity of early-stage development.

This article discusses how the early integration of highly experienced personnel—particularly individuals combining scientific, regulatory, and CMC expertise—can substantially reduce development risk, compress timelines, and preserve capital. Concrete examples are presented illustrating how early strategic decisions related to formulation, manufacturability, analytical strategy, and regulatory planning may prevent costly delays, repeated studies, clinical holds, or failed technology transfer activities.

The discussion further highlights how investors and pharmaceutical partners increasingly evaluate the proven track record of leadership teams as a surrogate marker of execution reliability and asset de-risking potential. In this context, experienced personnel are not merely operational contributors but strategic value creators capable of accelerating milestone achievement and enhancing partnering attractiveness.

Ultimately, this work proposes that in the modern biopharmaceutical environment, the long-term success of a start-up is determined not only by the quality of its science, but also—and perhaps more critically—by the quality, experience, judgment, and interdisciplinary integration of the people responsible for its execution.

Please note that drawing from nearly three decades of experience as a consultant in the life sciences industry, this article presents a perspective on the critical importance of experienced multidisciplinary personnel in biotechnology start-ups. The opinions expressed represent the author's professional interpretation and experience accumulated over more than 28 years in pharmaceutical and biotechnology development and may not necessarily reflect universally shared views within the industry.

The Evolution of the Biotechnology Start-Up Model

Over the past two decades, the biotechnology ecosystem has evolved considerably. Historically, many

biotechnology companies were created with the long-term objective of independently commercializing therapeutic products. Today, however, a large proportion of start-ups operate under a markedly different model in which the primary objective is to generate sufficient value for licensing-out transactions or acquisitions during early clinical development, most commonly after Phase 1 or Phase 2 studies.

In parallel, the design of early clinical development programs has also evolved significantly. Traditional Phase 1 studies performed exclusively in healthy volunteers were historically intended primarily to evaluate safety, tolerability, and basic pharmacokinetics. While this approach remains highly valuable for initial safety assessment, it generally provides little or no information regarding potential therapeutic efficacy. As a result, many biotechnology companies are increasingly incorporating patient cohorts during Phase 1b multiple ascending dose (MAD) studies in order to generate early "signals" or "trends" of efficacy.

This hybrid approach may contribute to earlier proof-of-mechanism assessment, improved translational understanding, and preliminary clinical differentiation versus competing technologies. Importantly, the generation of early efficacy-oriented data may substantially contribute to de-risking development programs from an investor and partnering perspective. In an environment where licensing discussions and company valuations frequently occur before completion of later-stage clinical studies, the ability to demonstrate not only safety but also early evidence of biological or clinical activity may significantly improve financing opportunities, partnership attractiveness, and overall market confidence.

Haut du formulaire Bas du formulaire Under this model, the perceived value of a company depends less on eventual commercialization potential and more on the credibility of the development strategy, reduction of technical and regulatory risk, and confidence in the execution capabilities of the organization. Consequently, the quality and experience of the development team have become central determinants of valuation.

Scientific Innovation Alone Is No Longer Sufficient

Even though scientific innovation remains the foundation of all therapeutic advances, it should be kept in mind that modern drug development has become highly multidisciplinary and regulated that scientific excellence alone can no longer guarantee success.

A highly innovative life science technology may still fail because of:

- poor druggability and manufacturability,
- inadequate formulation strategy,
- insufficient analytical characterization,
- regulatory deficiencies,
- scalability issues,
- or weak clinical development planning.

In many instances and taken together, these above failures are not directly related to biology itself but rather to inadequate anticipation of development complexity.

The Increasing Complexity of Modern Drug Development

The development of contemporary therapeutics has become significantly more complex than in previous decades. Life sciences' landscape makes it particularly evident:

- monoclonal antibodies,
- antibody-drug conjugates,
- RNA therapeutics,
- gene therapies,
- cell therapies,
- highly potent compounds,
- long-acting injectables,
- and complex biologics.

Nowadays regulatory expectations now contain:

- more extensive CMC packages (mainly because of complex druggability),
- comparability exercises (the process defines the product, and process may and will change from the bench to the clinic),
- immunogenicity assessments,
- advanced analytical characterization (mainly due to more complex delivery systems),
- extractables and leachables (mainly due to increasing injectable technologies),
- process validation,
- data reliability irrespective of development scales.

As a result, early development decisions may have long-term consequences extending far beyond initial proof-of-concept studies, transferability from the bench to GLP/GMP facilities and then repeatability, reproducibility over the different scales and non-clinical/clinical development steps.

Why Proven Experience Reduces Development Risk

A recurring observation within the biotechnology sector is that experienced teams consistently reduce execution risk.

Professionals who have previously:

- advanced compounds into clinical trials,
- interacted with regulatory agencies,
- managed manufacturing campaigns, toxicology and clinical studies
- overseen technology transfers,
- prepared IND/CTA submissions,
- or supported licensing transactions,

often possess the ability to anticipate challenges before they become critical.

This anticipation capability is particularly valuable because many development failures are preventable

rather than scientific inevitabilities, or lack of clinical efficacy despite strong preclinical data.
Investors increasingly recognize that a strong management and development team may substantially increase the probability that a promising scientific asset will ultimately reach meaningful value-creating milestones.

Time as a Critical Financial Variable
In biotechnology start-ups, time is directly linked to financial survival.

Every additional month of development may result in:
- increased cash burn,
- shareholder dilution,
- delayed partnering opportunities,
- and reduced investor confidence.

Consequently, preventable delays become extraordinarily expensive.

For example, an inadequate early formulation strategy may later require:
- reformulation,
- additional toxicology studies,
- repeated stability studies,
- new GMP manufacturing campaigns,
- or bridging clinical studies.

Such issues may delay development by 12–24 months while consuming millions of dollars in additional capital. Experienced drug development professionals frequently provide value precisely by preventing these delays from occurring.

The Strategic Importance of Regulatory and CMC Expertise
Many start-ups continue to underestimate the strategic value of regulatory sciences and CMC expertise during early development, especially by considering new drug delivery systems where lack of specialized regulatory guidelines strongly recommend an early dialogue between sponsor's and agencies. It will help to bridge the gap between all the steps that are involved in translational research and may avoid several pitfalls that may occur down the road. Again, taken together the time allowed for a pharmaceutical technology to go from the bench to the clinic may not only be shorter but also risk mitigated from both regulatory and efficacy standpoints

Regulatory professionals are often perceived as administrative contributors involved primarily during submission preparation. And based on the above, experienced regulatory and CMC professionals' influence:
- study design,
- analytical strategies,
- impact on PoM efficacy and cGLP toxicological profiles
- risk mitigation,
- manufacturing approaches,
- and agency interaction strategies.

Similarly, modern CMC activities are no longer limited to manufacturing support. They now represent a core strategic pillar capable of determining:
- product feasibility,
- scalability,
- reproducibility,
- commercial attractiveness,
- and regulatory credibility.

This is particularly true for advanced therapeutic platforms where manufacturability itself may become a major development hurdle (such as phages, solid lipid nanoparticles, modern combinational products….).

Human Capital as a Driver of Valuation
In licensing discussions and investment evaluations, pharmaceutical companies and financial groups increasingly assess:
- leadership credibility,
- operational experience,
- regulatory history,
- and execution/proven track records.

A company led by individuals with prior successful development experience is frequently perceived as less risky than a company relying solely on highly innovative science.

In this context, experienced personnel become strategic assets capable of increasing company valuation even before major clinical milestones are achieved.

This phenomenon explains why many successful biotechnology companies recruit former pharmaceutical industry leaders, senior regulatory experts, and experienced professionals at very early stages of development.

Common Organizational Misalignments in Start-Ups
Despite what is described above and broad recognition of development complexity, many biotechnology start-ups continue to prioritize organizational structures centered primarily around discovery science.

For example
- physicians may be recruited very early,
- while formulation scientists, CMC strategists,
- toxicology experts,
- regulatory experts,
- or global pharmaceutical development specialists,

are integrated much later.

While clinical expertise is clearly important, many early-stage programs remain primarily dependent on:
- proof-of-mechanism,
- developability,

- formulation feasibility (that may impact drastically toxicology results),
- manufacturability,
- and analytical robustness.

As therapeutic technologies become increasingly sophisticated, the difficulty associated with formulation and manufacturing continues to increase significantly. Consequently, delaying the integration of experienced development professionals may substantially increase technical and financial risk.

The Modern Paradox: Brilliant Science Can Fail Because of Poor Execution

One of the major paradoxes of the modern biotechnology industry is that many scientifically promising assets fail not because of poor biology, but because of inadequate execution.

Examples include

- poor druggability that will generate poor in vivo results (PoM and cGLP toxicology)
- manufacturing failures,
- inability to scale production,
- regulatory holds,
- analytical inconsistencies,
- inadequate comparability packages (situations where a company fails to generate sufficient evidence to Convincingly demonstrate that a product remains comparable after a manufacturing, process, formulation),
- or insufficient understanding of long-term product stability, reproducibility, reliability.

These issues frequently emerge late in development when correction becomes extremely expensive (up to redo cGLP toxicology studies).

In contrast, experienced multidisciplinary teams are often capable of identifying such risks early enough to avoid major downstream consequences.

Pharmacoeconomics and competitive positioning: an increasingly critical area that should be considered as early as possible

In addition to scientific and regulatory complexity, modern biotechnology companies must increasingly integrate pharmacoeconomic and competitive landscape considerations at very early stages of development.

A promising technology may still struggle commercially if:

- It offers limited differentiation,
- Enters an overcrowded therapeutic space,
- Or fails to demonstrate meaningful clinical or economic advantages compared with existing therapies.

Consequently, start-ups must now address strategic questions very early, including:

- What is the intended line of therapy?
- Which marketed products will serve as comparators?
- Is the technology truly disruptive or primarily a “me-too” product?
- Will payers perceive sufficient added value?
- Does the technology improve efficacy, safety, compliance, or total healthcare costs?

These considerations are becoming increasingly important because future pharmaceutical partners and investors often evaluate not only scientific feasibility but also commercial positioning and reimbursement potential.

For example, a highly complex and expensive therapeutic platform may generate significant scientific enthusiasm while remaining commercially unattractive if:

- manufacturing costs are excessive,
- reimbursement pathways are uncertain,
- or clinical differentiation versus standard-of-care therapies remains marginal.

Similarly, the emergence of numerous competing technologies within oncology, immunology, and rare diseases has considerably raised the threshold required to demonstrate meaningful innovation.

As a result, early-stage strategic planning must now integrate:

- Clinical differentiation,
- Market access considerations,
- Payer expectations,
- Competitive intelligence,
- And long-term pharmacoeconomic viability.

This further reinforces the importance of multidisciplinary teams capable of integrating scientific, regulatory, manufacturing, clinical, and commercial perspectives simultaneously.

CONCLUSION

The concepts discussed in this article may not appear revolutionary to experienced professionals within the pharmaceutical and biotechnology sectors. Indeed, many stakeholders already recognize that successful drug development requires more than scientific innovation alone. However, despite this broad acknowledgment, a significant number of biotechnology start-ups continue to be structured primarily around scientific excellence while underestimating the strategic importance of early-stage drug development expertise.

In practice, many emerging companies are still founded and initially driven by brilliant scientists whose discoveries may possess genuine disruptive potential. Yet, seasoned professionals with extensive experience in drug development, regulatory sciences, formulation, manufacturability, and translational development are

often integrated too late in the process—or are recruited based on titles rather than practical development experience.

For example, early executive hiring frequently prioritizes clinical or medical profiles, such as physicians, even when the immediate developmental challenges remain centered around proof-of-mechanism, pharmaceutical developability, manufacturability, analytical characterization, or formulation feasibility. In many modern therapeutic modalities—including biologics, complex injectables, nucleic acid therapies, antibody-drug conjugates, and other advanced platforms—the increasing technological sophistication of drug products has made pharmaceutical development and CMC strategy substantially more complex than in previous decades. Consequently, the ability to successfully formulate, characterize, manufacture, and scale these products has itself become a major source of developmental risk.

Under these conditions, early strategic decisions made by experienced drug development professionals can profoundly influence program timelines, regulatory credibility, financing requirements, and ultimately the overall valuation of a company. Conversely, inadequate early-stage expertise may generate delays, repeated studies, manufacturing setbacks, regulatory deficiencies, or avoidable destruction of shareholder value.

This perspective does not seek to diminish the central importance of scientific innovation, which remains the foundation of all therapeutic progress. Rather, it emphasizes that in the contemporary biopharmaceutical environment, scientific excellence alone is no longer sufficient. Increasingly, sustainable success depends on the integration of multidisciplinary expertise capable of transforming promising science into a robust and executable development strategy.

Based on nearly three decades of consulting experience in the life sciences industry, the author believes that the future success of biotechnology start-ups will increasingly depend not only on the originality of their science, but also on their ability to assemble experienced teams early enough to anticipate complexity rather than react to failure. Proactivity being the key word.