Qualio

Securing funding for your life science start-up

How growing life science businesses can attract investments and acquisitions

Table of Contents

Key stats	3
The roadmap	4
The state of life science investment in 2023	5
The flight to quality	8
Don’t neglect your ecosystem	14
Brush up on your pitch	18
Get non-dilutive funding too	20
10 top tips to secure life science investment	21

Funding is the lifeblood of a fledgling life science company.

Whether it's venture capital investment or full-on acquisition, catching the eye of a backer holding the pursestrings can be the difference between your product reaching patients or collapsing into nothing.

But times are tough. American healthcare VC funding fell 25% in 2022, a trend echoed worldwide. As belts tighten and cheap money vanishes, only standout start-ups with clear ability to outstrip the pack will be rewarded.

Qualio works with hundreds of ambitious, growing life science companies battling to get to market - so we know what works when it comes to proving the quality of your operation and unlocking crucial funding.

This guide breaks down everything you need to know to lift your company to the next level.

Meg Sinclair
Quality Operations Manager

Key stats

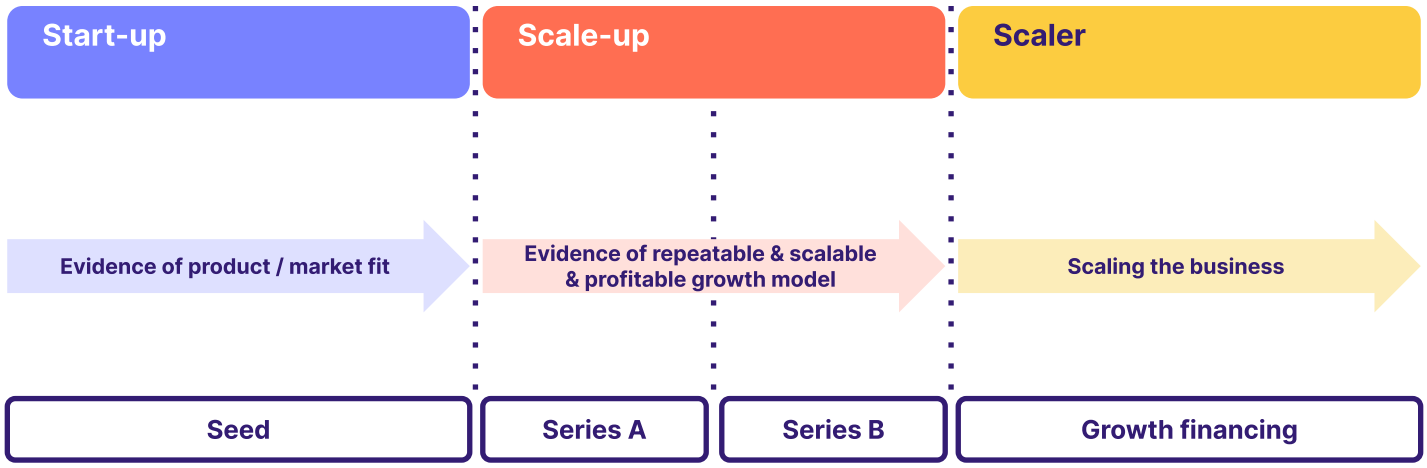
> *90% of start-ups fail, because of 'self-destruction rather than competition'*
>
> **— Startup Genome Project**

> *$21.8bn of funding was awarded to US life science companies in 2022, down from $28.3bn in 2021*
>
> **— Silicon Valley Bank**

> *75% of VC investments generate no return for investors*
>
> **— Harvard Business School lecturer Shikhar Ghosh**

> *Life science investors are pivoting towards fewer, higher-quality investments in response to 2023 market uncertainty*
>
> **— Life Sciences Review**

The roadmap



Bootstrapping a life science company is *hard*, and external private equity (PE) investment is often a natural part of the modern medical device, pharmaceutical and biotech trajectory.

The three milestones of seed, Series A and Series B funding form the typical funding objectives for nascent life science companies.

Other organizations might opt for a merger/acquisition strategy instead, aiming to get their entire operation subsumed into a pre-existing entity.

Of course, both strategies can be pursued simultaneously, and the effects and the 'to do' lists of both approaches are identical: to demonstrate a reputable, trustworthy and viable high-quality operation for a funding party to plow dollars into.

> ***Companies don't die from dilution, they die because they run out of cash.***
>
> **— Steve Gillis**

The state of life science investment in 2023

Investment and acquisition activity has dipped from its impressive peak in 2021, and there's no longer the cheap capital nor the appetite to put it to work that got us there.

But there are still some reasons to be bullish about the resilience of the life science industry. A predicted general fall in valuations should mean an increase in deal volumes, and there's a trend towards more early-stage investments and portfolio-broadening product acquisitions which suggests more start-ups and scale-ups than ever before are attracting attention.

As risks and economic uncertainty remain high, more nimble and creative de-risking collaborations with these smaller players could rise at the expense of flat-out acquisitions. Co-commercialization, options and spinoffs are all possibilities to help get less mature R&D assets to market.

Perhaps most significantly, it's a relatively small number of dealmaking actors pulling the strings of life science investment. Bain & Company found 65% of European and American life science deals were fed by the same 50 funds.

Competition to land on the radar of these kingmakers, who are themselves seeking shelter in safe high-quality investments, will therefore remain intense.

Medical devices

Elective surgery and procedure activity still hasn't recovered to the levels seen before COVID-19, but it's getting there.

This recovery should help spur fresh medical device market demand after a slump in 2022.

In vitro devices, on the other hand, could profit from a new era of decentralized diagnostic testing ushered in by the pandemic - as long as the drop in COVID-19 testing demand is properly rerouted into new opportunities.

SaMDs and IoT wearables continue to provide the cutting edge of the medical device sector, and could benefit from fresh investor attention as the 'techification' of life science continues and 'digital therapeutics' spread far and wide.

Contract organizations

The splintering of the industry from monolithic domination into a chain of 'connected and interdependent' smaller entities was noted by our CEO Rob Fenton in 2022.

That trend looks well set to continue, with fresh outsourcing of research and manufacturing making CROs and CMOs ever more viable investment targets. Their track record of outperforming the general market doesn't hurt, either.

Pharmaceuticals and biotech

The Inflation Reduction Act passed in mid-2022 could make considerable waves in this sector for American companies.

The new deflationary requirement to renegotiate Medicare prices for prescription drugs will dampen margins and therefore valuations and forecasts.

2022 saw a clear movement towards smaller, early-stage deals, and the upcoming expiration in this decade of patent protection for many popular drugs, including some blockbusters, should strengthen the need to augment enterprise pipelines by adding promising new IP, disruptors and patents from early-stage targets. As Labiotech puts it, 'capital will target innovation'.

Over 30 new drugs were approved by the FDA in 2022, proof that activity in this sector remains high and productive.

The flight to quality

The premiums needed to get deals done make it essential for investors and acquirers to see the promise of full realization of underwritten value. The 'flight to quality' is an investment phenomenon as old as capitalism. A more disciplined, risk-based and quality-focused approach to capital allocation is certain in the face of recent economic headwinds and decreased liquidity – so it falls to you and your business to prove value and quality to a level not necessarily required in previous years.

Of course cash flow, balance sheets and a strong product have their place. But a neglected differentiator – your organizational approach to quality management – will separate the good from the great vying for investor attention.

Backing a winning horse is notoriously difficult, and your investors will be watching intently for a gap, oversight or unrealistic assumption which gives them an excuse to turn you away. Putting them at ease by anticipating and answering these reservations is key. Consider these questions:

1. How will your business manage the increasingly complex quality and regulatory demands of the life science market and secure approval to operate in your territory?
2. How have you prepared for potential contingencies: macro- and micro-economic developments, supply chain evolution, market shifts, regulatory change?
3. How does your product incorporate user needs and requirements for robust market fit?
4. How will you ensure you meet or surpass your timelines for getting to market and monetizing?
5. How can you prove the baseline is in place for sustained, long-term growth and profitability?

To compellingly answer all of these questions and position your business as a high-quality investment, a strong quality management system is vital.

This shouldn't be confused with bare-minimum *compliance*. Depending on your country of operation, complying with FDA, MHRA, EMA or TGA requirements is an essential prerequisite.

As competition for investment increases, simply getting an ISO certificate on the wall or securing a 510(k) clearance won't help you stand out – these benchmarks are now widely expected.

Taking things a step further by *accelerating* and *systematizing* quality is where the greatest potential for differentiation comes.

What does this mean in practice?

Because quality management has a deep impact on all corners of the modern life science business, from manufacturing and growth to customer retention and profitability, digitizing your quality approach unlocks a string of knock-on benefits which increase your company's overall attractiveness to investors and acquirers.

Electronic quality management systems (eQMS) offer digital control and centralization of key quality management elements like:

- **Documents**
- **CAPAs, investigations, event responses**
- **Training**
- **Design controls (for medical devices)**
- **Analytics & reporting**
- **Suppliers**

A single source of cloud-based digital truth connecting these elements allows a life science business to work in a consistent, repeatable and structured way no matter where its workforce is physically based.

Ditching cumbersome paper and spreadsheets sharpens, controls and accelerates access to information. Eliminating admin headaches and freeing up headspace allows careful long-term planning to continuously improve the products and services offered to customers.

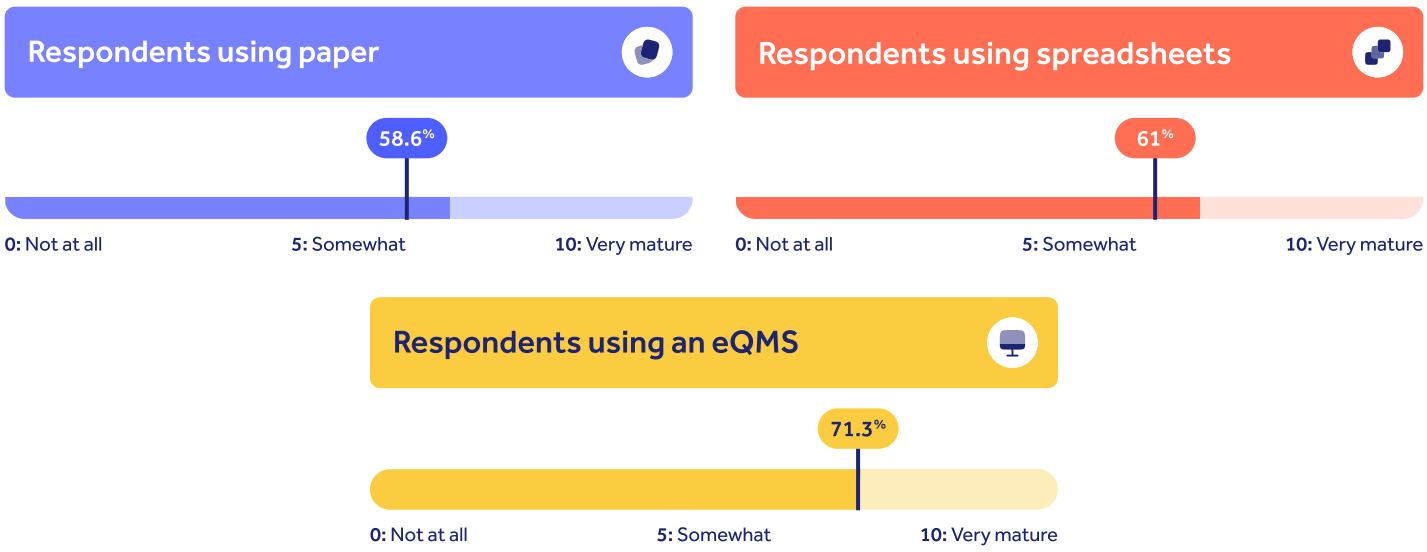
And as things do inevitably go wrong in early stages, digital workflows allow internal and customer feedback, complaints and improvement suggestions to be actioned and resolved much more quickly to get things optimized and back on track.

Benefits of an eQMS investment include:

- Doubling (or more) of product release velocity
- 90% reduction in regulatory process time
- 95%+ reduction in admin time
- Leaner operation with 4-5 FTE spends mitigated

The effects of digital quality on operational maturity and effectiveness were made clear in our 2023 survey of thousands of international life science quality professionals:

"How would you rate the maturity and overall effectiveness of your quality management system?"



> *Quality management boils down to one core element: reliable repeatability. Success relies on repeatability.... market competition begins and ends with quality.*
>
> **— Jerry Foster**

Taking these effects together, an eQMS empowers growing life science start-ups and scale-ups to make quality the driver of a rapid, efficient, continuously improving operation that helps them stand out as a quality investment with the metrics to match.

In the complex web of risk management activity which comes as company and investor pursue a deal, those who can show a properly implemented eQMS, all else being equal, will realistically beat a company with a legacy approach to operational quality every time.

Put yourself in your investor's shoes.

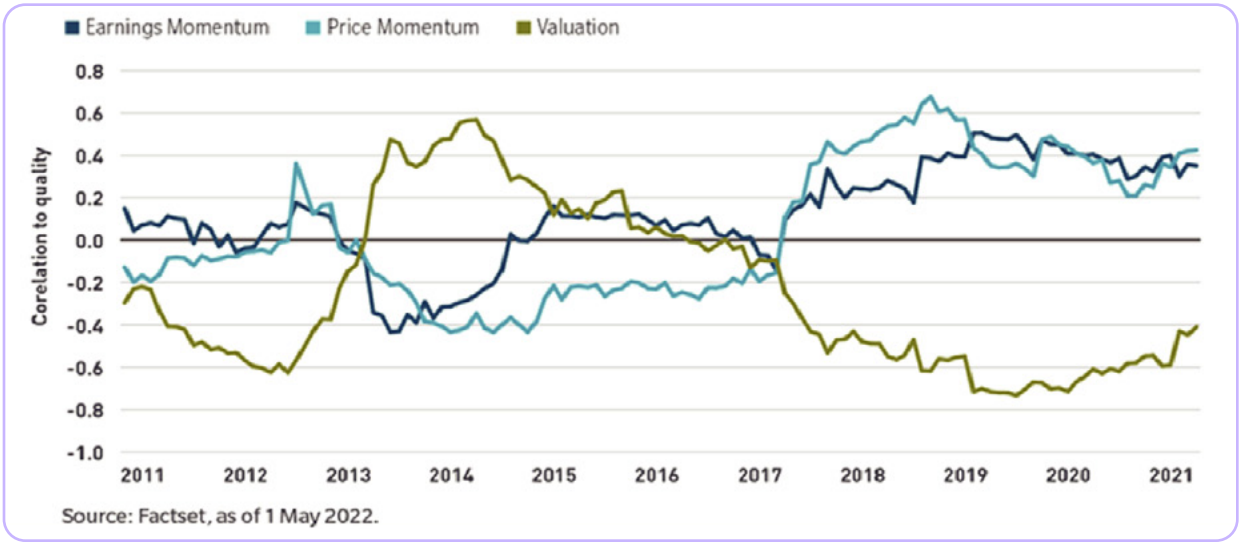
Would you be more likely to invest in an organization, in a highly regulated, life-or-death industry, that can prove:

- Its information streams and documented data are well-managed?
- Its staff are fully trained, confident and competent?
- Its suppliers are properly managed and onboarded (more on that below)?
- Its medical device has mature design controls integrating user requirements into the lifecycle of the product?
- Its processes are executed with speed, traceability and control?

The answer is more than likely yes, since these crucial operational building blocks naturally impact the strength of your product *and* its ability to fly through clinical trials and regulatory checks – not to mention the broader investment quality considerations of your risk profile, financial strength, growth, gross profitability, and so on.

It's why MFS found a market correlation between recognized company quality and both earnings and investment price momentum going back to 2019. And even though quality and valuation have been negatively correlated for a while, with cheaper 'value' companies driving investment trends for a few years, there's evidence of that changing as investors, once again, 'fly to quality' in riskier post-COVID times.

Quality correlates with market performance and momentum



Source: Factset, as of 1 May 2022.

> *It's far better to buy a wonderful business at a fair price than to buy a fair business at a wonderful price.*
>
> **— Warren Buffett**

Case study: quality as competitive advantage

2018	Biopharmaceutical company 30 Technology founded
2018-2020	Legacy quality system of paper and spreadsheets
Nov 2020	Head of Quality & GxP Compliance Karen Hue appointed
Jan 2021	eQMS adopted: 97% reduction in quality process time, accelerated market readiness, 5 effective FTE workloads performed by a digital platform
Jul 2021	ISO 13485 accreditation secured 6 months early for medical device product
2021-2022	Nitrous oxide respiratory platform enters clinical trials
Apr 2023	Antimicrobial wound care business divested to Convatec for $220m

Learn more

Don't neglect your ecosystem

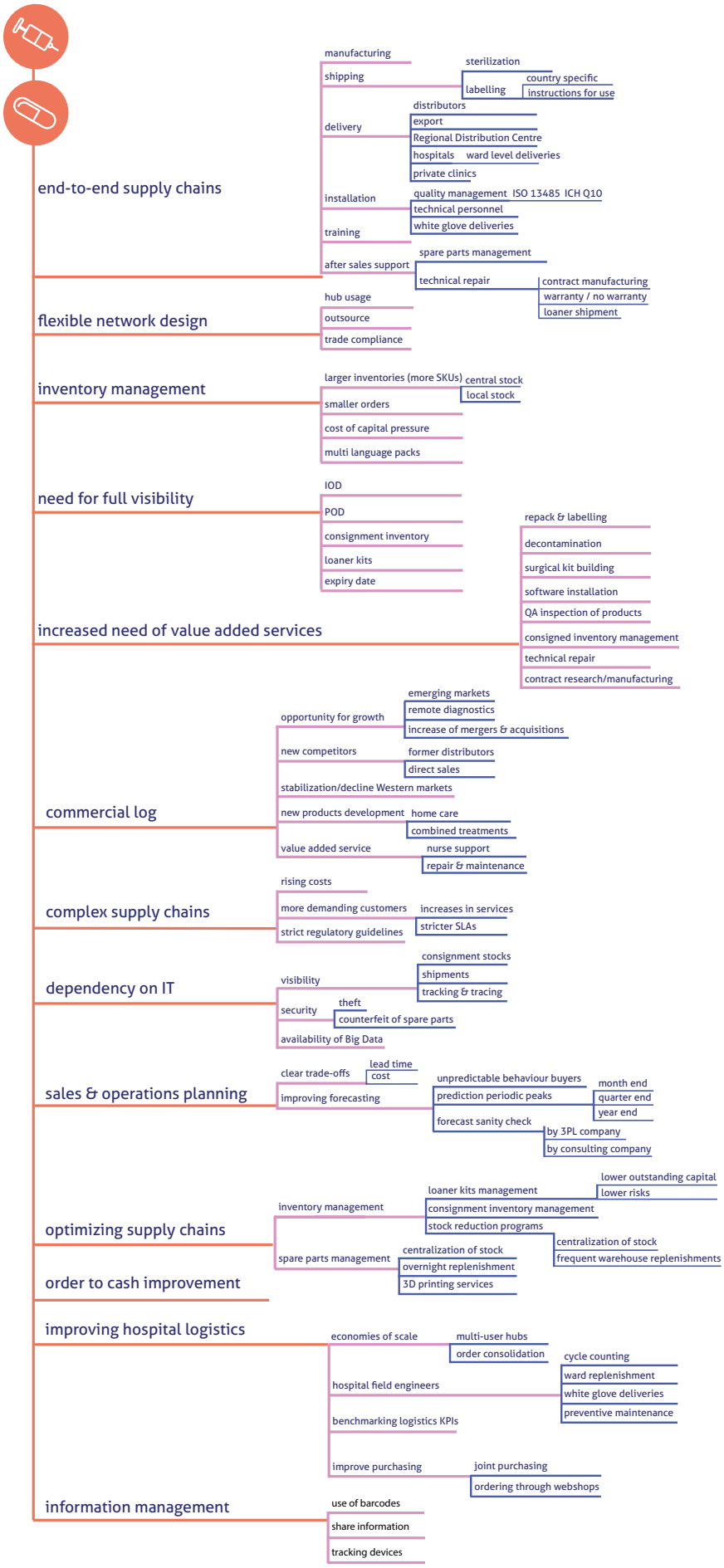
For mergers and acquisitions, proof that you can plug a resilient, secure supply chain into a larger operation can be a key factor that pushes your business ahead of the pack.

Both physical and data security are of paramount significance to acquiring entities in search of geographic expansion.

For investors, too, a well-managed and risk-based supply chain strategy is proof that you have your house in order and are well-positioned for future operation.

Read 4 scary stories of company collapse triggered by quality mishaps ›

The modern medical device or biopharma organization has a web of considerations stretching beyond your four walls:



And start-ups and scale-ups hungry for investment fall into the same mistakes when dealing with their suppliers and interested parties:

1. Lack of fully binding quality agreements
2. Poor supplier-customer communication
3. Reliance on regulatory oversight: no independent verification
4. One-size-fits-all supplier strategy
5. No on-site audits of key suppliers
6. Weak purchasing controls
7. Undiversified supply chains

Your quality and viability as an investment target are only as strong as the weakest link in your operation. Proving a vibrant, risk-based supplier management strategy is in place will help your company sail through due diligence activities.

On top of that, you should consider at all times the complex interrelationships of modern life science. It's highly unlikely that your product has been developed entirely in-house: contract organizations, hospitals, academic institutions and other third parties are all likely to have their say in the lifecycle of an R&D asset.

Download the essential guide to life science supplier management ›

Planning well ahead and mapping out clear, sensible legal relationships governing topics like ownership, IP, confidential information, milestones and royalties is therefore vital.

Both upstream and flowdown material agreements should be carefully constructed, preventing any potential future obligation landmines that an investor or acquirer could balk at.

Morgan Lewis defines the life science investment 'poison pill' as:

> ***a clause or provision in an upstream agreement that creates problematic flow-down obligations - for example, a very broad obligation to share confidential information, know-how, inventions, future patents, improvements, etc. with an upstream licensor, unrealistic milestone and royalty obligations that overly burden the margins given development costs, or issues related to the diligence obligation to develop and commercialize the asset. If the risk is too high or the upstream licensor won't renegotiate to limit these rights, a future acquirer or partner may walk from the deal...***

As with your supply chain, you should therefore pay close attention to your binding agreements from the very first day of your company operation, considering the long-term impact of your third-party relationships and how you'll effectively manage the risks connected to them.

Brush up on your pitch

We've seen the strategic. Now for the tactical.

Life science founders and innovators are usually highly intelligent, driven and, of course, scientifically minded, with multiple degrees and a deep grasp of niche scientific and technical concepts.

None of that necessarily corresponds to communication that investors will appreciate as you walk into the room and pitch your company.

Your investors don't necessarily care about the deep scientific minutiae of your product (a broad overview of functionality and value is often more appropriate) and don't necessarily want to wade through pages of complex information. They aren't scientists and they want the bottom line in a matter of minutes.

- What are you pitching?
- What's the market fit?
- And how will it generate value/save costs compared to current treatment offerings?

The format of any investment pitch deck should be concise, pointed and directly targeted at these questions while delivering emotional value to your listeners.

In this regard, life science companies are better positioned than, say, a financial or agricultural pitch: your product could save lives, ease pain, stamp out disease or raise quality of life, so don't be afraid to call it out.

Tell a story with a beginning, end and hook. Make the format easily accessible, clear, and as pictorial as you can. Pull clinical data in, but summarize it to quickly get to the bottom line of what it means. Touch on unmet human needs and bring your proof of concept to life. If you already have customers and patients, tell their story and how you've helped them too.

Qualio customer Heather Underwood, CEO of EvoEndo, went through her own Series A funding journey in 2022 and offered this tip:

> ***What makes EvoEndo unique is the strong story we have and the very important clinical need we're addressing.***
>
> ***A strong value proposition, a story, and the evidence to support what you're doing, all go a long way.***
>
> ***Lots of our investors are family offices, committed philanthropic individuals who really care about the mission. It's important to them we get our product out to the world.***
>
> ***That's really what made raising our funds possible.***

And once you've walked out of the room, ensure your 30-second elevator pitch lives on in the memories of your audience.

For all of this, a marketing hat is invaluable. Run your deck past a marketer or two before it ever gets in front of your would-be investors.

Listen to our podcast episode with Dr. Jen Baird, who's done it all: raised $30m of angel and VC funding, gave her investors a 5x return, then went back and started a new venture with Series A all over again

Get non-dilutive funding too

Investors prefer to jump onto a moving ship. Securing other forms of funding proves the potential and promise of your business and makes you more likely to unlock fresh rounds of investment.

In the US, the life science industry receives some $3bn in non-dilutive grants and contracts every single year. The National Institute of Health (NIH) alone awards over $1bn in Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants.

There are also corporate and nonprofit grant options to consider. Pfizer, for instance, offers corporate grants in various areas, from RFP-based competitive project grants to quality improvement initiative funding.

Top tip

Once you have non-dilutive funding to show off, make sure you break down how you spent your grant or award, as well as the value you've seen and delivered from your funding.

Securing a slice of non-dilutive funding for your business proves your 'grantsmanship' and demonstrates that you've already convinced a room of experts that your company and your product and services are worth supporting – even without surrendering a portion of ownership in return.

Science offers a comprehensive list of grant targets.

Watch our webinar recording: How to fund your life science start-up with non-dilutive funding

10 top tips to secure life science investment

01. Make quality your competitive differentiator as the 'flight to quality' takes wing

02. Get robust QAgs in place as you build supplier relationships

03. Start looking for both dilutive and non-dilutive funds as early as possible – the process will take longer than it did in past years

04. Ensure your upstream and flowdown agreements won't turn off investors

05. Let your marketing team see your investment pitch before your investors do

06. Consider outsourcing to a CMO or CRO to speed things up

07. The later the development stage of your product, the lower the risk and the higher investment premiums. Accelerate your route to market with quality by design

08. Use flatter valuations and more sober market conditions to work harder on your processes and the problem you're trying to solve

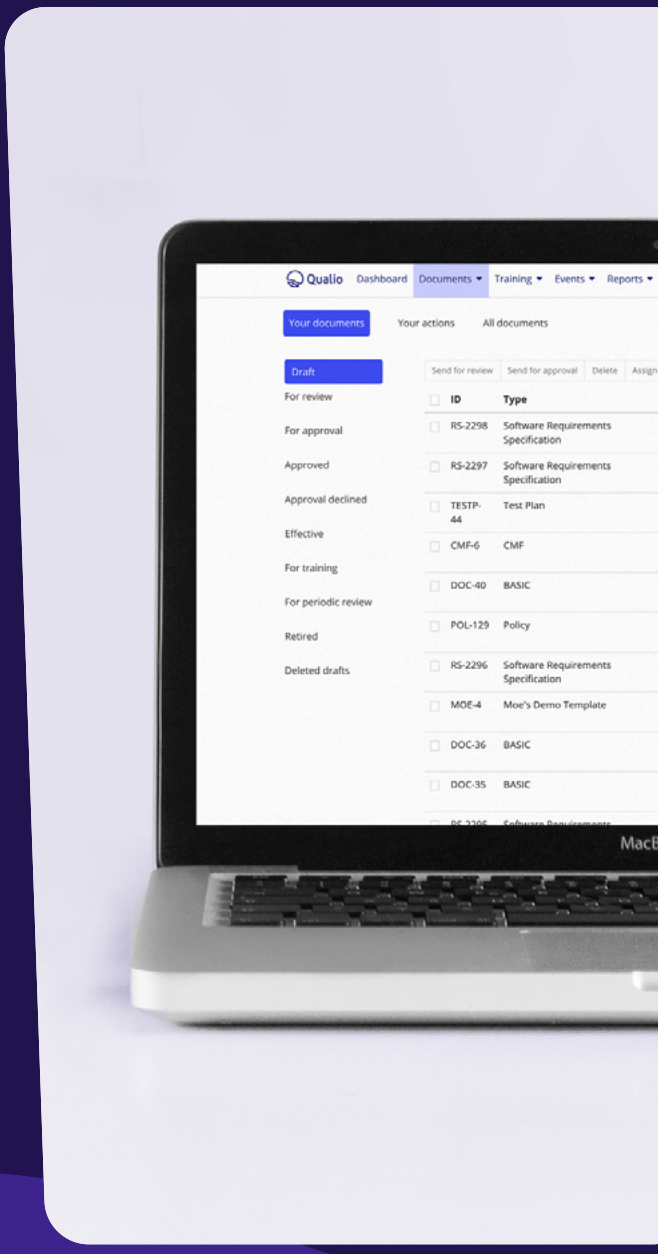
09. Investors are getting pickier and may not want to invest in every product winding its way through your R&D pipeline. Consider splitting them up into smaller companies if it makes sense to do so

10. Invest in digital tools to maximize operational maturity

Qualio

Ready to stand out from the pack with world-class quality?

Schedule a demo with us



Call us today
1.855.203.2010 • +353 1 697 1522