



White Paper

# Biotech Roadmap

## Four Easy Steps to Commercialization

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This series provides a roadmap for a start-up biotech company as it moves to the commercialization of its first product. By examining the growth stages, we will identify critical points in the drug approval process. The series will scrutinize the systems needed to support the biotech through its lifecycle, the key decisions, and provide knowledge gleaned from those who have successfully taken their product to market. Using a scalable methodology, implemented in phases as the company grows; the roadmap is a guide on how to manage different business processes that occur with each growth stage. The roadmap helps biotechs manage the transition between growth phases, with minimum capital costs.

When it comes to information technology requirements, the biotech industry is unlike any other. After all, how many industries must manage complicated processes such as clinical trials, regulatory compliance, and contract manufacturing while hiring hundreds of expensive specialists over a 10-year product development span and spend \$400 million with little or no revenue to show for it? While the stakes are enormous — in 2000, life science ventures captured more than \$1 billion of investment seed capital — a successful company can provide significant return on early shareholders' investments.

To be successful, however, a biotech company must efficiently and effectively manage four main growth stages as it moves from startup to product commercialization. A key enabler of efficient and effective growth is the adoption of IT strategies specific to each stage. The four growth stages are:

1. Startup
2. Partnerships and trials
3. Submission and commercialization
4. Sales, manufacturing, and beyond

## Growth Stage One The Start-up

Stage 1 biotechs are normally strong in science, fair in business knowledge, and dismal in the areas of regulatory compliance, clinical trials, product-quality assurance, and information technology. Yet by the time the biotech submits its first new drug application (NDA) to the FDA, it will have spent at least \$3 million on IT alone. Historically, financial managers assumed responsibility for technical decisions, but this approach has often failed to recognize the complexities of the challenge. Today's executives at biotech startups must plan for rapidly evolving information systems, facilities, and supply chain, and develop an IT strategy that aligns with the overall business plan.

IT is no longer about merely providing computer-related services. It's about managing content, especially content tailored to regulatory requirements and submitted electronically to government agencies. Companies such as IBM, Oracle, Sun, Motorola, and Agilent have created sophisticated tools that make the drug-discovery process more efficient. But managers must

decide which systems — computers, databases, software, servers, and networks — are needed now and which systems can be added later.

On their own, scientists will tend to invest in isolated systems that have worked for them in the past without considering how the data from disparate systems will be integrated. Either through external consultants or hiring specialized staff, a startup will need to find people with systems experience as well as solid understanding of the scientific aspects of the business.

There are three main areas that a startup's IT infrastructure must harness: data, people, and cash. Data issues revolve around intellectual property and its protection. These assets must be quantified and protected. With people, the significant issues are: How many are generating data, what are they doing with the data, and how many are on the payroll? With cash, the important concerns are how much is going out, how much is coming in, and finding new sources.

### Growth Stage Two Partnerships and Trials

At this point, the company is making decisions on how to develop a drug and take it to market. These decisions will affect how much money needs to be raised, what equipment and systems have to be purchased, and what staff or services will be needed.

A significant milestone in Stage 2 growth is filing an investigational new drug (IND) application with the FDA. This is usually the first contact with the FDA and the time to define regulatory strategy. It is recommended that the company adopt an electronic submission strategy at this stage. Building the necessary IT system and process controls early is easier and cheaper than waiting until later in the drug-development process.

Internally, the Stage 2 biotech is still science focused as it hires more specialists. It's rapidly moving from ideas to proof-of-concept, and more money is being invested in labs and research work. Quality assurance (QA) is becoming more important as the company begins formally recording the process of how it does its day-to-day activities.

True, the FDA requires documentation of these procedures, but it's also simply good business practice. At this stage, electronic document management systems should become standard tools for handling document review, notice of expiry, and approval workflow, all of which let staff concentrate on content.

Other new functions emerge in Stage 2, and critical strategic decisions have to be made. The biotech's systems must be capable of producing good information to help decision-making. To reduce risk and expense, many Stage 2 biotechs choose to outsource professional services such

as preclinical and clinical research, legal counsel, and business development. However, outsourcing adds project management and cost-control functions to the growing list that now includes quality control, quality assurance, and regulatory compliance.

With research and finance dominating the biotech's priorities in the early stages of growth, the importance of information systems is often overlooked. As functions increase, management should solicit strategic advice from its IT department. For example, when selecting a contract research organization (CRO) to conduct clinical trials, the FDA now requires the biotech to show it has conducted a proper site/vendor audit to prove the CRO meets 21 CFR Part 11 regulatory requirements. IT and QA staff should conduct these audits together to measure the CRO's technical and procedural capabilities.

#### Collaborate or Die

Each new external partner brings its own unique challenges, and IT must be consulted each time to avoid expensive mistakes. One biotech, for example, signed an agreement with a CRO only to discover six months later that the format of the data to be delivered was incompatible with the biotech's systems. All the deliverables that had been negotiated were focused on scientific and financial concerns, with no consideration of the data-delivery format.

With more partners and suppliers, the Stage 2 biotech needs to consider how its systems will interact with external systems, and the company must implement collaboration tools. Practical IT functions such as document management help with collaboration, save money, and can be

implemented simultaneously to meet regulatory compliance.

To save money, time, and resources, the same tools with consistent formats need to be implemented across the enterprise. The senior IT person must be empowered to vet all requests and group them together for larger project consideration according to the priorities of the management team and the business strategy. Otherwise, decentralized systems develop far too easily.

One method of centralizing decisions is to form a committee to develop an information systems strategy. A handful of members can represent a cross-section of the company and help set the direction and priority of current and future IT projects. This group should also discuss Part 11 risk assessment to scrutinize the impact of each new system's effect on regulatory requirements.

# Growth Stage Three

## Submission and Commercialization

The Stage 3 biotech is constantly questioning what will make money and what will make for long-term business viability. Now the defining state of the company is preparation for submitting an NDA to the FDA. This mammoth publishing task involves the coordination of the entire company, its outsourcers, and its partners.

Internally, the Stage 3 company is facing explosive growth of information systems (to handle time sheets, contracts, projects, laboratory monitoring, security, etc.), and for the first time there is rapid expansion of non-science staff.

Supply-chain management becomes more complex due to outsourcing, and production planning has to be exact as lead times for ordering are measured in months. The FDA requires consistency and control over the manufacturing process, and the uniformity of each product used in trials must be proven and documented. The biotech must also show that it has a high degree of confidence that trials are being conducted appropriately. Quality assurance is crucial, as the FDA requires vendor audits as proof that all contractors adhere to protocols and agency guidelines.

Intellectual property management becomes more serious, too, as additional indications and patent protection extensions are being examined. Marketing activity increases as the biotech looks at different applications for its drug and estimates the patient population while simultaneously scanning for potential competitors. On the operations side, quality control, staff training, facility management, and project management continue to consume more time.

### The Trials of Clinical Research

In Stage 3, the biotech may have between 100 and 200 employees. Human-resource information systems (HRIS) are now quite complex as stock options, salaries and benefits, and projects must be managed. With unique hiring needs, the biotech should task IT with developing a resume- and skills tracking system to improve assignment of specialists and to take advantage of all staff capabilities. This helps dynamically reassign staff as projects are canceled and new research is started.

Reliable IT systems must also be implemented to manage the outsourcing of trials. Once a CRO finds patients who meet trial protocol, there's an enormous amount of information to record and track: patient and hospital name, patient's medical information, doctors' notes and files, data on patient reaction to product, and more. Plus there are legal contracts concerning experimental trials for each patient.

Each trial site and all the medical research conducted must be audited for submission purposes. A uniform process is required to demonstrate to the FDA that procedures have been followed, and to document what was done if they weren't. It's critical that standard operating procedures (SOPs) are created, as the FDA will audit the trial sites themselves during its review.

Collaboration tools enable real-time recording of data and provide up-to-the minute information on clinical trials. These tools produce cleaner, more accurate data that are easier to publish during the drug-approval process. If everything goes right with the NDA submission, Stage 3 growth pretty much concludes with FDA approval of the drug.

### Growth Stage Four Sales, Manufacturing, and Beyond

FDA approval of the biotech's leading drug is finally complete. Until now, the company's primary focus was science, and everything was built around the NDA. Now what?

The new emerging function that occurs in Stage 4 growth is complex, but a pleasure to deal with: revenue and cash-asset management. Money is now coming in, and an IT system is required to invoice, bill, and record deposits for thousands of clients. This new system must be integrated with existing systems.

This drastic change in the company's mandate has other significant effects on IT infrastructure. To handle the supply chain, production planning, trial management, project management, and all the other aspects that rely on information systems, IT will need to step up the real availability of data and build an enterprise resource planning (ERP)-style solution.

In the past, all data were targeted for one audience: the FDA. Now, in this stage, corporate data have a new audience: the management team. Rather than ask for proof of safety and efficacy, the management team will ask questions like: How are sales in Europe? Does the current rate of production match forecasts for growth in demand?

A Stage 4 company's data requirements shift from actively tracking projects and trials to actively forecasting future sales — a difficult transition that needs to occur in less than six months.

Consider: If a drug takes three months to manufacture, how does a company make sure it has enough supply to meet demand? Building a multimillion-dollar inventory before approval is a

huge gamble, but enough of the drug has to be available for customers. This may significantly hit the bottom line.

Million-dollar questions requiring the most accurate information possible are being asked by the executive team. For example, after three months of sales of its drug, the biotech has a million dollars in revenue — is it time for a shareholder dividend, or does that money go into research? The IT system needs to provide answers in real time.

#### Superior IT, Superior Information

Superior information and enhanced marketing forecasts lead to superior decisions. If the IT systems are built right the first time, efficiencies are gained and money is saved in the long run. In addition, collaboration, data sharing, and knowledge management tools will have captured a significant amount of intellectual assets, and it should now be possible to go back through the data to gain insight for new projects.

Critical questions can be answered. How much did it cost to develop the drug? How were resources allocated? Most important: How much more will it cost to develop another drug? The executive team now has a way to back up its gut decisions because projections can be quantified with existing data.

Business intelligence reporting emerges as a key function in the commercialization stage, and IT must give executives the tools and the training to run their own reports. Usually, the easier a reporting tool is to use, the more complex the IT. Knowledge management tools are key, as data produced by each department (marketing, manufacturing, etc.) must be linked. This enables

an executive to easily produce informative reports on the status of the entire enterprise.

Capturing intellectual assets through knowledge management tools can yield something else that is hugely valuable: additional scientific discovery. With properly organized data from research, development, and clinical trials, the biotech can

use data-mining techniques to go back and “discover” new indications.

One more thing a well-evolved IT structure can provide: Many biotechs have found that by building intranets that link databases, their scientists can become aware of projects other scientists have already tried, thereby avoiding the same mistakes.

## Four Growth Stages of Biotech

Growth Stage One, The Biotech Start-up (50 employees and under)	Growth Stage Two, Trials and Partnerships (50 – 100 employees)
<p><b>Biotech Characteristics</b></p> <ul style="list-style-type: none"> <li>• Startup research</li> <li>• Small number of staff</li> <li>• Raising capital for projects</li> <li>• Accumulation of costs,</li> <li>• Pre-clinical trials,</li> <li>• Research of potential commercial compounds.</li> </ul> <p><b>Emerging Functions</b></p> <ul style="list-style-type: none"> <li>• Financial and investor relations</li> </ul>	<p><b>Biotech Characteristics:</b></p> <ul style="list-style-type: none"> <li>• Partnering begins</li> <li>• Proof of concept (pre-clinical/clinical trials)</li> <li>• Documentation of results</li> <li>• Strategic and marketing relationships</li> <li>• Time and materials costing for partnerships</li> <li>• Continued raising of capital.</li> </ul> <p><b>Emerging Functions:</b></p> <ul style="list-style-type: none"> <li>• Business development</li> <li>• Quality assurance</li> <li>• Quality control,</li> <li>• Regulatory compliance</li> <li>• Financial information systems</li> <li>• Planning and budgeting</li> <li>• Project management and cost control</li> </ul>
Growth Stage Three, Submission (100-300 employees)	Growth Stage Four, Commercialization (300 plus employees)
Leading up to first NDA	Post NDA approval
<p><b>Biotech Characteristics:</b></p> <ul style="list-style-type: none"> <li>• Single product</li> <li>• Multiple studies for multiple indications</li> <li>• Limited contract manufacturing to support trials</li> <li>• Marketing and supply chain managed through strategic partners.</li> </ul> <p><b>Emerging Functions:</b></p> <ul style="list-style-type: none"> <li>• Supply chain management</li> <li>• Marketing</li> <li>• Intellectual property management</li> <li>• Risk assessment</li> <li>• Contingency planning</li> <li>• Human resource information systems</li> </ul>	<p><b>Biotech Characteristics:</b></p> <ul style="list-style-type: none"> <li>• Contract manufacturing</li> <li>• Marketing</li> <li>• Sales and distribution through strategic partners</li> <li>• Same product</li> <li>• Multiple indications</li> <li>• Royalty payments and cost sharing</li> </ul> <p><b>Emerging Functions:</b></p> <ul style="list-style-type: none"> <li>• Management of revenue stream</li> </ul>

# Hardware Requirements for Biotech Roadmap

## Growth Stage One: Building Infrastructure

Predictably, the basic office infrastructure, which includes desktops, network switches, cabling, tape backup, and a centralized data file server, comes first. Second, an application server that will host both e-mail and a simple accounting application to manage payroll and accounts receivable. Laboratory equipment such as flow cytometers, HPLCs, or gene sequencers often require specialty work stations for collecting and analyzing the results.

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## Growth Stage Two: More Boxes

Cash is still king for the fledgling biotech. New systems initiatives are purchased to fill immediate needs and do not necessarily integrate with each other. Web, document / content management, and Intranet server purchases allow the company to store and effectively share corporate data but result in hardware used specifically for lone applications. Laboratories are growing to include Quality Control and that requires purchasing more equipment. In order to organize the near overwhelming data, the instruments/workstations need to be connected to robust servers containing relational databases to store and index research data.

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## Growth Stage Three: Overwhelming Infrastructure

When a company moves into Stage three, the IT server room might contain 10, 20 or more servers with various operating systems, software applications, database, and data formats. Software applications now being purchased are not necessarily stand-alone applications, but tend to be sophisticated add on style modules to existing applications. Supply Chain Management extends the Financial System, a publishing software add on enables document management applications to publish e-CTDs, and LIMS systems combine various laboratory databases into one controlled environment. These new applications enable reflection on the whole hardware / software infrastructure as it is possible to combine similar applications. Though more software will be added, the amount of hardware does not proportionally grow with it. Consolidated software will require less, but more robust, hardware.

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## Growth Stage Four: Sustaining Growth

By the time of FDA approval, few new applications are added and there is a shift towards reporting on existing data and information. Moore's law has taught us that hardware capabilities double every 18 months, and the same holds true for the generation of corporate data. If not done in Stage 4, companies will be consolidating their data into more sophisticated SAN or NAS style storage configurations thereby allowing for dynamic allocation of drive to applications as required.



**For more information**

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