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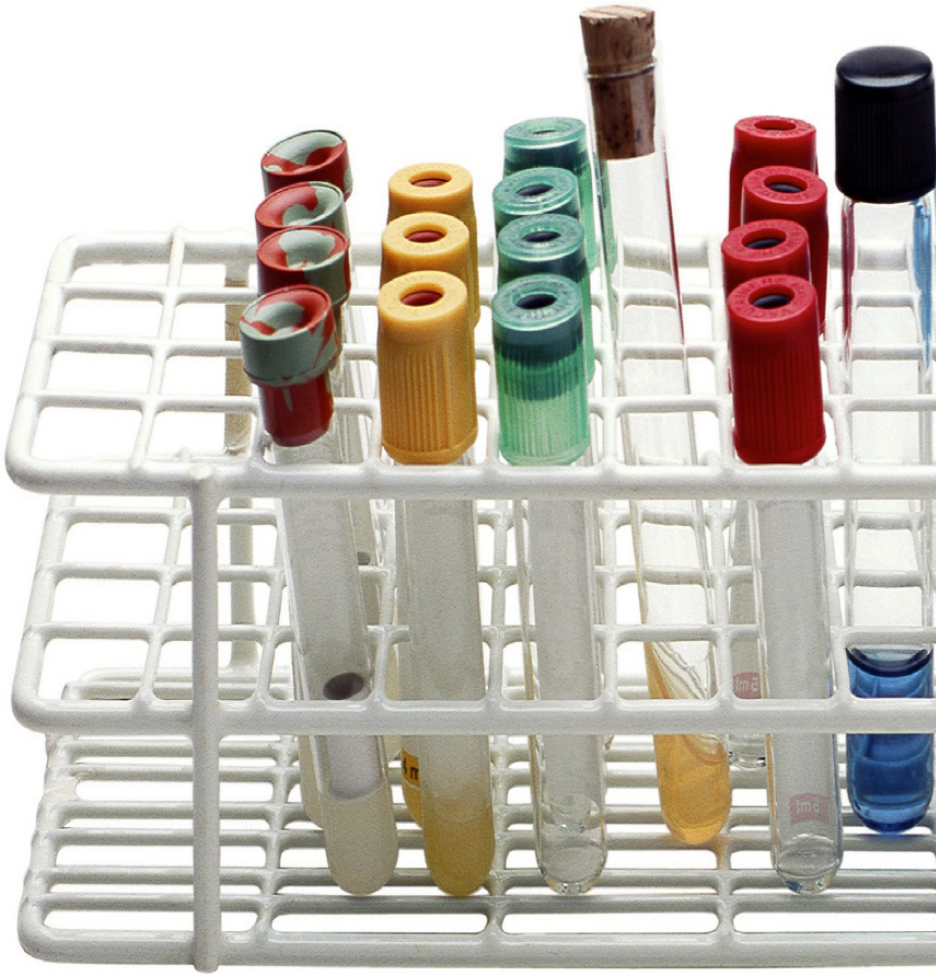
Operating Under Consent Decree
Managing a Life Sciences Company through a Major Regulatory Action



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Tarnished reputations, lost sales, massive fines and remediation expenses, cultural change and hostile working environments, diminished morale, legal disputes, employee retention and product shortages are common challenges faced by Life Sciences companies operating under Consent Decrees (CD). There is no aspect of the business that is unaffected, and the impacts can extend to customers and patients as well. It takes a broad-based effort to effectively address the concerns of regulatory agencies while simultaneously preparing the company to manage its current business as well as their mid- and long-term operations. The effort involved goes well beyond simply developing and executing a remediation plan and should consider the strategies and tactics to design and manage an organization that not only has to survive as the remediation efforts are underway, but also thrive in the future.

A typical CD lasts three to five years and can cost upwards of $500M in fines, penalties, remediation expenses and lost sales. Beyond the significant and broad economic impact, it can also damage a company's culture, image, customers and patients.

Overview of a Consent Decree Environment

A Consent Decree is a legal agreement between a company and a US regulatory agency that is enforced by the US Department of Justice after court approval. In exchange for agreeing to the terms of the Consent Decree, which is often a result of one or more inspections or investigations by the regulatory agency, a company may be allowed to continue manufacturing and selling products, but under heightened regulatory scrutiny and with significant limitations on how and when product can be released to customers. In some cases though, production is halted completely at the impacted sites until the remediation efforts are concluded. There are usually signals, like recalls and Warning Letters, that precede a major agency enforcement action like a product seizure or injunction, which culminate in a Consent Decree. Those signals are increasing in number and they highlight major compliance breakdowns. As a result, major enforcement actions leading to a Consent Decree are on the rise. Monetary fines imposed through civil and criminal penalty actions also demonstrate increasing regulatory scrutiny and regulatory agency activity.

Between 2004 and 2010, FDA issued an average of 550 Warning Letters a year and that number more than tripled in 2011 to 1720 . Likewise, there has been a steady climb in medical device recalls in recent years with over 650 in 2007 rising to over 1270 in 2011. There have also been increases in drug and biologic recalls during the same period[1].

In addition to the regulatory impact of major enforcement actions, monetary fines, and warnings on companies, there are usually several other government and non-government impacts on companies and their employees. Product supply and patient access to critical drugs or medical devices can also be affected by regulators, leading to broader social and public health repercussions as seen in a recent suspension of drug manufacturing by a contractor responsible for oncology products; this action caused many oncology patients difficulty in finding adequate supplies of life-saving drugs. Even when the drugs involved are not life-saving, popular products have failed to reach the consumer, which can negatively impact brand loyalty as alternatives are sought. Government agencies can also require third-party oversight at the manufacturer's expense, and they may increase the frequency and duration of their inspections. In certain circumstances, civil and criminal legal actions are being directed, not just at corporations, but also at individuals for non-compliance with the law and regulations.

When major regulatory action is imminent or has been undertaken, it has the potential to not only impact a company financially, but also impact the organization's cultural foundation and its customers' and patients' health and welfare for years to come. Employee morale can be impacted by a hostile environment and people may start leaving the company. When a Consent Decree hits, dozens of contractors and/or new employees may join the organization and roles and responsibilities will rapidly change.

It is important that companies invest in preventing major regulatory action from being initiated and seek assistance at early warning signs. However, when it does occur, it is equally important to be able to minimize as much as possible the impact to the business. We have seen that many companies are reassessing their compliance practices, embracing Quality by Design, improving quality controls, adopting forward looking compliance metrics and emphasizing a culture that respects and builds quality into everyday business operations. Addressing these areas proactively vs. dealing with them after a regulatory action occurs can be critical to avoiding the negative financial, cultural and social impacts. However, being able to continue operations when a major regulatory incident has occurred is probably more critical.

[1] Source: Publicly available information on the US FDA website. Please see http://www.fda.gov/ICECI/EnforcementActions/default.htm for further information; Includes WLs issued by all centers

Effectively Managing a Business in a Consent Decree Environment

Whether currently under Consent Decree or on a path toward it, our client engagements have given us an opportunity to see how a wide variety of diverse manufacturers and executive management teams respond to this very difficult environment. It is common that companies use a point solution or functional response approach to addressing the situation. While Regulatory and QA experts and leaders are a critical part of the response team, the magnitude of the problem can require a holistic response that coordinates the remediation effort with the ongoing business operations. It is critical that senior executives are involved in the day-to-day decision-making and planning required to address the remediation activities while maintaining viable, compliant business operations. While Quality and Regulatory executives need to make time-sensitive, compliance-driven decisions, those decisions should concurrently be sustainable and viable for the business over the long term. Sustainability can be accomplished by having an executive team that represents all aspects of the business dedicated to the remediation efforts such as the allocation of resources between remediation activities and the core business operations, and the development of a compliant and sustainable operating model going forward. Some considerations for such an operating model include:

Balancing the significant remediation requirements of a CD with the needs of the base business is essential for long-term company survival.

- Making the right thing to do the easy thing today—if compliant behavior and actions are too cumbersome and complex, there may be a higher probability of failure
- Avoiding processes that are duplicative or non-value added
- Identifying and addressing the underlying root causes of process and compliance challenges, rather than addressing just the symptoms by throwing additional resources at the problem
- Developing and delivering meaningful, relevant training and education related to quality, compliance, and Consent Decree activities (Example training modules: Consent Decree onboarding, Quality System Element Overviews, Standard Operating Procedures, or Compliance Requirements)
- Fostering an environment that enables employees to provide information about potential compliance issues without fear of retribution
- Establishing formalized communications between diverse stakeholders with differing visions of success—a healthy tension between different functions is a good thing as it often leads to a mutually-acceptable, long-term outcome

Thoughtful Planning is Key: You are in the Consent Decree Business Now

In the normal course of business, a company should have been able to perceive signals of significant upcoming problems prior to being subject to a Consent Decree. Increasingly, some companies are leveraging and enhancing current risk management processes and procedures to monitor activities that are indicative of underlying quality or compliance problems and raising them to senior management attention. For example, complaints from employees or human resource activity regarding disagreements with superiors can have their origin in ethical issues in manufacturing processes and procedures. By not investigating, a company may be missing an opportunity to uncover festering compliance and quality issues that could lead toward a major enforcement action if allowed to continue. Identifying the issues can allow a company to plan for corrective action, assess potential safety impacts and evaluate different options before regulatory action has been initiated. The impact can be significant, as discussed further below, and companies should keep in mind the collateral damage to the business.

Should the worst case scenario occur and a company finds itself under Consent Decree, the company should accept the fact that it is now in the Consent Decree business for the foreseeable future. When a company enters into a Consent Decree, its business environment is dramatically changed, virtually overnight. A common reaction by senior executives is to try to manage the Consent Decree as a 'project' and keep the rest of the business operating as near to normal as possible. Business as usual most likely will not work.

As a company begins down the long road to compliance under the restrictions placed upon it by the Consent Decree, it is critical to keep in mind the time frames and scope involved. Typical Consent Decree remediation efforts last three to four years, though the "planned" remediation period may be shorter.

For the first 18-24 months of operating under the Consent Decree, the project can be treated as a basic operational business and take advantage of opportunities to manufacture product as they arise. Leadership should embrace the fact that without meeting a Consent Decree's requirements, there may not be a business to run. For example, many companies under Consent Decree may be able to manufacture product in a relatively normal fashion, but releasing this product for sale is an entirely different matter. The decision to manufacture product at risk is a business decision that involves business leaders, manufacturing personnel and QA/RA. Once the risk management aspects of production have been agreed upon and decisions have been made, these decisions need to be communicated to employees and contractors in all departments of the company and management should provide clear direction on what the manufacturing go-forward plan is and how product disposition will be handled. It is also critical to develop plans that balance the compliance needs and the business needs going forward. Processes have to become not only compliant but also lean and sustainable, allowing the company to plan, make, and deliver its products and services profitably while meeting

> A Consent Decree cannot be effectively addressed overnight or without transparency. Expectations for both the near and mid-term should be adjusted and clearly communicated to employees, investors, customers and patients

its obligations to customers, patients and regulators. Accomplishing this is not easy, but processes should be designed so that the compliant way is the easy way, too.

Often, a company's culture and behaviors will need to change as they may have played a significant role in leading a company into a Consent Decree. Creating a culture that respects and demands compliance from all functions within the business can be crucial to long-term survival. Successfully doing this may require:

- Establishing unquestionable direction and support for quality and compliance from the CEO level through written communications, sufficient resourcing, and decision-making from product development through distribution.

- Placing Compliance officers and QA executives in senior positions in the company with direct access and reporting authority to the chief executive officer and the audit committee

- Defining what compliance means for every role in every function in the organization and communicating new expectations to employees

- Holding the entire organization accountable for compliance and quality and reinforcing the desired, compliant behaviors through appropriate incentives

- Changing the focus of operations from a product release mindset to a high quality, compliant product release mindset

- Ensuring that employees at all levels understand the value of compliance and embrace this is as a core attribute of their culture and behavior

- Evaluating the impact to compliance and quality when making business and operational decisions

As a result of the complexities of doing business under Consent Decree, successfully operating in this environment may require a comprehensive and integrated approach to managing all aspects of the base business along with the remediation effort. At the core of this is a strong focus on governance that is measureable and accountable for results. The governance structure for the Consent Decree effort should bring together the right leaders with appropriately defined scope of responsibilities. This focus and clarity, along with goals being set that are aligned with leadership at all levels of the organization, both at the facility under Consent Decree and the organization as a whole, can be crucial for success. Deloitte's Framework for Effective Consent Decree Management includes nine critical components as outlined in Table 1 and Figure 1:

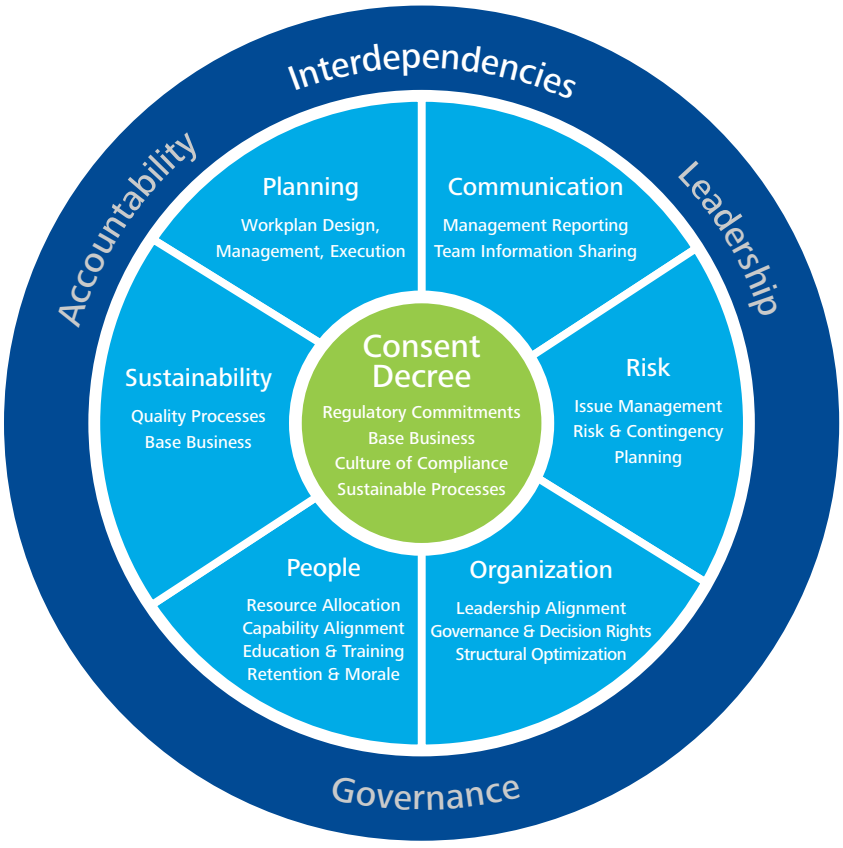
Table 1: Nine Critical Components for Effective Management while under Consent Decree

Critical Components	Business as Usual	Consent Decree Environment
Leadership	• Leaders and managers with the right functional skills and experience	• Leaders and managers with the right functional skills and experience • Ability and courage to drive significant operational, business and cultural change. Embrace compliance by leading by example.
Accountability	• Accountable for functional and overall business goals	• Accountable for functional and overall business goals • Accountable for remediation goals and compliance requirements
Governance	• Implement and maintain structure and process that drive actions, decisions and behaviors to support critical business objectives	• Implement and maintain structure and process that drive actions, decisions and behaviors to support critical business objectives • Consider the impact on quality and compliance • Balance potentially conflicting interests between leaders managing a function with base business demands as well as a component of the Consent Decree.
Planning	• Capabilities to plan and execute under normal business and operating conditions	• Capabilities to plan in a highly uncertain, ever-changing environment that is significantly more restrictive than in the past.

Critical Components	Business as Usual	Consent Decree Environment
Organization	• An organization designed to optimally achieve key business and financial goals as primary objectives	• An organization designed to optimally achieve key business and financial goals as primary objectives without sacrificing quality or compliance.
People	• The best and the brightest in their field of expertise, focused on bottom line results	• The best and the brightest in their field of expertise, focused on bottom line results while emphasizing quality and compliance.
Communication	• Internal and external communications focused on business results and financial forecasts	• Communications focused on achievable commitments to regulators; business results and realistic financial forecasts • Frequent updates to the organization on the progress and implications of the Consent Decree.
Risk	• Primary focus on identifying and mitigating risks to meeting business and financial objectives	• Primary focus on identifying and mitigating risks to quality and compliance as well as business and financial objectives
Sustainability	• Design and implementation of processes, policies and practices that drive long-term profitability	• Design and implementation of processes, policies and practices that drive quality and compliance • Continually assess and modify processes, policies and practices to drive long term profitability while maintaining quality and compliance.

In addition to these individual components, it is important to manage the interdependencies that exist between them. Not only will the remediation efforts take careful and detailed coordination with the base business, but each of the components above cannot achieve the desired results without alignment with and support from the all of the others. This integration process can be essential to surviving in the Consent Decree and is often an area where companies fail to place enough emphasis.

Figure 1: Framework for Integrated Consent Decree Management



Planning: Prepare for the long haul

- **Develop planning and process capabilities tailored towards the new reality:** This reality will be constantly changing in the near term, but the long term results of the Consent Decree may impact the total capacity of a company's facility (as compared to pre- Consent Decree manufacturing levels) due to new, more complex compliance driven procedures, and additional control points and documentation requirements. We often find that one of the root causes for major non-compliance issues is operating the plant "full out" to meet production targets or focusing operation goals on releasing product vs. manufacturing quality product. This can lead to compromises on quality and compliance. Production plans and targets—and the resulting sales and financial forecasts—should be adjusted to reflect this new environment.

- **Utilize tools and technologies:** Identify tools and technologies that can effectively support compliance and provide visibility to performance against the quality and compliance objectives. For instance, tools can help companies monitor processes that may become bottlenecks (e.g., GMP document review and approval, training, facility and equipment remediation activities). Dashboards and metrics to measure and report on performance are also essential. Technology changes which are not necessary to address compliance issues or support the remediation program should be postponed until the CD has been successfully completed.

- **Avoid excessive focus on the near-term:** Instead of focusing on the current week or month, develop detailed plans for future quarters and years. The extended horizons can lead to better resource planning, interdependency identification and management and capital budget pre-allocations. For inherently uncertain tasks, develop ballpark estimates to manage risks and interdependencies with built-in allowances for the inevitable unknowns and "gotcha" moments.

Production planning and release rates are often the first casualties of the new operating environment. Long-term lower output and longer release cycles are often a difficult pill to swallow. Take your medicine and plan for realistic goals that may likely be significantly different from yesterday's results.

Production and release capabilities will be impacted. In addition to the fines and penalties a company may pay, significant revenue loss from product shortages — which has topped $100M in a number of cases — may be likely

- **Reevaluate and redesign existing internal processes:** Quality System processes and procedures, such as corrective and preventive actions (CAPA), investigations, document review and approval, validation processes, and their supporting technologies, were not designed for the volume and stress a Consent Decree will cause. For example, the volume of GMP-related documents and investigations driven by the Consent Decree and flowing through QA can be 50-100 times the volume from the base business. Additionally, a breakdown in the Quality System most likely contributed to the situation the company finds itself in. It is important to assess and modify these processes to accommodate the increased workload and more stringent requirements while eliminating faults or shortcomings that can negatively impact quality and compliance. One of the typical problems faced by companies under Consent Decree is dealing with the pendulum swing that often accompanies the remediation effort: a non-compliant, production-focused operation that over the years swung the pendulum further away from quality and compliance suddenly overnight swings in the direct opposite direction, focusing on quality and compliance while neglecting production. While this may be necessary to deal with short-term issues, over-restrictive procedures leaning heavily on oversight and reactive methodologies can be unsustainable over the long haul. One company had to add additional warehouse capacity to hold quarantined product while CAPA's and investigations were being closed. Once these restrictive processes are in place, they can be very difficult to back away from. Companies should develop compliant processes that are sustainable, even if the development process takes a bit longer.

Organization & People: Focus on culture and resource management

- **Select the right leadership and organizational structure:** Appoint leaders that are aligned with the delivery objectives of the Consent Decree. Balance the importance of past experience with the ability to demonstrate key leadership skills necessary to drive change throughout the organization. Effective leaders will have the skills to manage in a complex, high pressure, regulatory-constrained environment.

- **Focus on governance and decision authorities:** It is important to design an organization and governance structure that clearly defines responsibilities, outlines interactions and hand-offs with existing governing bodies across the organization, and gives key personnel the authority and accountability needed for success. The committees and managers who oversee the remediation effort should report directly into the company's senior leadership. To allow for the needed structural changes, the strategic focus, charter and membership of executive committees may need to shift in light of the Consent Decree.

- **Decide where to put the best people:** Rather than assigning top talent to base business operations, consider deploying them on the more complicated and critical portions of Consent Decree commitments. The skills and capabilities of top talent should be assessed and assigned to successfully build, execute and sustain changes resulting from the Consent Decree and allocate the appropriate resources to the most critical roles. Consider appointing or hiring the best talent and problem solvers to address the challenge of the Consent Decree and try to avoid the temptation of placing talent in a role solely for their compliance or QA expertise, or experience in a Consent Decree. Finally, metrics for success should be determined and individuals regularly measured against those metrics in order to confirm that individuals are positioned in the proper roles and motivate to continue to drive value across the organization.

- **Develop plans for shared resources:** Resources required for remediation activities - such as facility and equipment remediation, documentation creation / approval, and training - often draw on the same pool of talent. These activities are usually needed by multiple workstreams, require similar resources, and have the potential to become major bottlenecks if not managed effectively. Planning for efficient use of these shared resources is a key to success.

- **Be prudent in using external help:** While under a Consent Decree, the number of external contractors may increase tremendously (e.g., advisors in quality, manufacturing systems, facilities, compliance, project managers, trainers, FDA representatives) and can raise headcount in some departments by 5-10 times. Plan to manage contractors proactively to ensure alignment to your objectives, culture and guiding principles. This can be accomplished by establishing clear goals and performance standards, frequently measuring and evaluating contractors against these standards, and keeping the number of vendors to a minimum to reduce variability. This will support quality levels, and help ensure your organization is receiving a consistent message from its business partners.

- **Focus time and attention on the importance of knowledge transfer:** Because of the volume of external contractors and the constant ebb and flow of project team resources, it is important that mechanisms be developed to enable the transfer of knowledge across team members. This can increase the effectiveness of onboarding and off-boarding processes, as well as confirm that knowledge does not leave the building every time a resource "rolls off" the project team.

- **Address impacts on culture:** The organization should have an increased focus on creating a culture of compliance. Consent Decree commitments can dominate many areas of the organization and dramatically impact the culture. Leadership should proactively monitor cultural changes stemming from execution of Consent Decree commitments, while simultaneously defining and shaping a future-state organization culture of quality and compliance.

Communication: Under commit and over-deliver

• **Develop a plan and a timeline that you are certain to be able to meet:** As you negotiate the settlement terms with FDA and develop your corrective action commitments, take care to anticipate and build in time for unforeseen delays. There is little to no advantage of giving FDA project timelines that are overly-aggressive and difficult to meet. One of the biggest mistakes clients make is the submission of a plan with a compressed and aggressive timeline that is unlikely to be met. Many companies have to go back to FDA to ask for additional time to implement plans because they underestimated the work and time involved.

• **Involve the most senior leaders:** In their anxiety around the future and the haste to appear responsive to the regulatory agencies, many executives task the development of commitment plans and timelines to the Regulatory and Quality team. While this may appear prudent on the surface, these individuals though very knowledgeable and skilled in regulatory compliance and quality principles, may not have the operational knowledge or experience when it comes to execution. The right mix of regulatory, quality and operational experience is necessary to develop pragmatic timeframes that recognize the realities of day-to-day operations. While this does not mean senior

executives marginalize the importance of the CD, many simply don't realize the magnitude of the impact to the base business and the critical need to manage both in an integrated fashion.

• **Develop a plan to inform internal stakeholders:** Execution of Consent Decree commitments is a long term journey that all employees need to participate in over several years. Informing stakeholders is important, and can be approached through the development of a plan to identify the communication needs of key groups and the channels that exist through the organization. A well-developed and executed communications plan can keep all relevant parties and governance groups informed during a Consent Decree. Considering the timing, delivery mechanisms, and information needs of each unique audience is key to delivering appropriate messages to keep employees informed and committed to the Consent Decree.

• **Enable team information sharing:** Inherent in the CD environment is the prevalence of interdependencies between all layers, including newly formed work groups, governing bodies, and leadership in the base business and the CD organization. An effective flow of information is important for identifying, escalating and resolving risks and issues. Developing formal processes and communication mechanisms can be critical to confirm action items are followed up, issues are escalated, and information is shared.

• **Manage and communicate schedule changes:** Delays are inevitable and can be expensive if the commitments made to FDA are not met. The financial markets follow Consent Decree issues closely, and FDA can mandate significant daily penalties for missed milestones. Stock prices typically decline in the days and weeks following the signing of a Consent Decree and can easily be in the double digits[2]. Further delays, fines, penalties and lost sales can have an even bigger impact to share price. These delays can also hurt a company's credibility with FDA and other stakeholders, and create more issues and problems for the employees dealing with day-to-day Consent Decree projects. By identifying potential delays early on and communicating to stakeholders proactively, the impact of these delays can be minimized.

Risk & Sustainability: Rethink the quality mindset and tailor to the core business

- **Understanding the Consent Decree's impact to your business can be essential for survival:** An organization should understand the operational and financial implications and effectively communicate to your customers and investors. These competencies may include a detailed understanding of how and when your organization will be able to produce and deliver products to customers and patients and what financial performance you can realistically deliver.

- **Build quality and sustainability into the process:** As quality standards, procedures, processes and associated documentation are revised, organizations should build quality into the process rather than using a post-facto "inspect quality" mindset. They also need to ensure the sustainability of processes going forward, and should not be overly focused on compliance, but focused on designing a system that is both compliant and viable from a business standpoint. To illustrate the importance of sustainability planning in the design of compliant processes, we have outlined two opposing case studies in Table 2.

[2] Source: BioPharm International, "After the Consent Decree – An Uphill Battle for Affected Companies", 1 Jun 2004, http://www.biopharminternational.com/biopharm/article/articleDetail.jsp?id=102280

Table 2: Consent Decree Case Studies and Outcomes[3]

	Business as Usual	Consent Decree Environment
Client Description	• Global Medical Device and Equipment Manufacturer facing a Consent Decree covering a major division and three manufacturing sites	• Global biologics manufacturer that received multiple, serious Warning Letters in consecutive years
Approach	• **Leadership:** Created Chief Quality Officer role reporting directly to CEO • **People:** Moved high-performing managers from prominent line positions to full-time Consent Decree management roles (i.e., no "day job") • **Planning:** Significantly reduced near-term production and release goals • **Communication:** Proactively shared plans and forecasts with customers and corporate parent, resetting expectations • **Sustainability:** New processes and procedures jointly designed across all functions, driving both compliance and sustainability	• **People:** Quality Staff levels rose from 175 to 370, complicating and slowing quality processes and creating a culture clash in the short term • **Planning:** Release rates significantly lagged production targets, resulting in 80% of product being quarantined and financial and customer commitments being missed • **Sustainability:** New processes and procedures designed with a sole focus on compliance, leading to a massive spike in workload and operational gridlock
Outcomes	• Successfully exited Consent Decree and regained position as global leader	• Corporate parent exited the business and sold off all assets

[3] Source: BioPharm International, "After the Consent Decree – An Uphill Battle for Affected Companies", 1 Jun 2004, http://www.biopharminternational.com/biopharm/article/articleDetail.jsp?id=102280

Impact on the Business

The most visible impact is to the companies' bottom line. Consent Decrees are often accompanied by financial costs that span the entire value chain of the company. Some common financial costs are surrender of profits, penalties/ fines, independent oversight fees, recalled/destroyed product, facility and labor overhead due to suspended operations, and lost sales. When added up this can easily exceed $1B for larger companies. There are also some examples of senior pharmaceutical executives being personally fined for non-compliance actions that occurred on their watch, an option FDA is likely to keep on the table for the foreseeable future. Senior level executives are oftentimes named in FDA injunction actions. Even after emerging from a Consent Decree the negative impacts on brand loyalty and eroded consumer confidence may never be fully restored. Greater emphasis should be placed on prevention by fostering a culture of quality and compliance and building it into the everyday work processes. Supplementary controls should be in place for early detection of quality and compliance issues so that corrective and preventive measures can be taken well before the situation results in a major regulatory action against the company. To provide incentive for avoiding major regulatory action select examples of recent Consent Decrees and their timing and impacts are listed in Table 3 below.

Table 3: Recent Consent Decrees and Their Impacts[4]

Company	Timing	Scope	Impact	Costs / Penalties
Pharma Company #1	1999 to 2003	Diagnostic tests manufactured in two facilities in Illinois	Approximately 75 out of 300 tests could not be sold in the US	• 100M immediate payout • $68M for contractors • $129M additional fine levied by FDA in 2002 for continued non-compliance with 1999 CD after 2001 follow-up inspection
Pharma Company #2	2002 to 2007	Facilities in Puerto Rico and New Jersey	Sites remained open with third-party oversight	• $500M disgorgement penalty and the potential for a maximum of $175M in additional penalties if the timelines were missed (did not occur) • $40M in lost sales due to termination of certain product lines • Approval of Claritin delayed one year, loss of revenue not determined
Pharma Company #3	2000 to 2006	Two Facilities in New York and Pennsylvania	Sites remained open with third-party oversight; One of the plants was later decommissioned and sold	• $30M disgorgement penalty and $26M in other fees and costs • $267M in fines paid in 2001 • Closure of two plants
Pharma Company #4	2005 to Present	GMP violations and manufacturing issues	Company to recondition seized drugs	• $650M bond posted pending resolution of reconditioning effort
Pharma Company #5	2006 to Present	Litigation resolution - infusion pumps	Company discontinued sales of this line of pumps	• Allowed to post a $20M letter of credit • $70M remediation cost charge

[4] Source: BioPharm International, "After the Consent Decree – An Uphill Battle for Affected Companies", 1 Jun 2004, http://www.biopharminternational.com/biopharm/article/articleDetail.jsp?id=102280

Company	Timing	Scope	Impact	Costs / Penalties
Biotech Company #1	2010 to Present	Fill/finish facility contamination and GMP issues	Uncertain/pending final settlement still being negotiated	• CD signed in Q1 2010 • $175M disgorgement paid in Q4 2010 ($15,000/day for missed deadlines)
Consumer Healthcare Company #1	2011 to Present	Three plants in Pennsylvania and Puerto Rico	Product withdraws and shortages; significant loss of market share; and third-party oversight	• $15,000/day for any missed commitments • $15,000 for each additional violation • Up to $10M in fines annually • Significant lost sales and incremental costs
Generics Company #1	2012 - Present	Manufacturing and GMP issues; data integrity issues; US and India facilities	Company relinquished 180-day marketing exclusivity for three generic drug applications	• Company to withdraw applications with data issues • $15,000/day • Up to $10M/year penalty if drugs distributed from Consent Decree sites • Up to $30M/year penalty if additional untrue statements are made to FDA

In addition to direct financial impact, other areas of the business may be affected just as significantly, including:

- Day-to-day operations: The normal paradigm for daily operations is efficient execution, active risk management, flexibility and decision-making, within the confines of long-standing and well-understood constraints. Now, with the black cloud of a Consent Decree visible as a permanent overhang, the paradigm can shift dramatically to one of conservatism, risk avoidance, bureaucracy, and micro-management of all aspects of operations and interactions. A clear understanding of the impacts should be developed to help ensure that operations are designed and managed for sustainability over the duration of the remediation and beyond. Both long-term and short-term views are important, as the effects will change dramatically over time.
- Innovation and value creation: A Consent Decree does not just affect marketed products or approved manufacturing facilities. There can be significant impact on a company's pipeline and its drug or device approval processes. In addition to reallocating limited monetary resources to remediate the Consent Decree, some companies have been forced to withdraw drug applications (e.g., ANDAs), pending independent review and successful remediation of the Consent Decree. Manufacturing facilities and staff can be forced to remain idle, while violations are addressed. Work-in-process products, raw materials and intermediates may stay unprocessed or expire as the investigations continue. FDA can, and often does, hold up the review process on pending applications for both drugs and devices until the company is back in compliance.

- Long-term impacts: As remediation efforts progress, executive roles and responsibilities will need to change, attitudes should adjust to the new reality, and building a culture of compliance will be important. Reaching these goals will not be easy, and morale may be impacted. While many employees start out optimistic and engaged, enthusiasm wanes over time, and the culture can become one of indifference and lethargy. This loss of enthusiasm can even lead to high performing employees leaving the company. This shift in attitude should be carefully monitored and managed in order to minimize the loss of these talented individuals. Also, the existence of a Consent Decree at a company can be a significant obstacle to the recruitment of skilled employees and managers. While it cannot be directly tied to a Consent Decree, it is interesting to note that a majority of companies that have engaged in a Consent Decree have subsequently been acquired.

Summary and Conclusions

For Life Sciences companies facing a major regulatory action such as a Consent Decree, business as usual is about to change significantly. Not only will the company have to engage in a costly and time-consuming remediation effort, but it will also have to continue to manage the business during a time of extraordinary change and upheaval. Successfully managing through this environment can require a number of critical focus areas and actions, some of which are listed below, as well as a business partner that has the capability and experience to guide a company through it. Deloitte's experience shows that companies can successfully navigate these challenges if they create a strong foundation to balance the remediation effort and base business. The following are summary points to keep in mind for companies entering a Consent Decree: Companies are most successful when they:

- Create a "Consent Decree First" culture and environment
- Be thoughtful and deliberate, because the Consent Decree is a marathon, not a sprint; the company is in the Consent Decree business for the long haul and should be managed with that reality in mind
- Manage FDA effectively with realistic project plans that can be exceeded with additional effort; project plans should not be reviewed and approved solely by business owners and compliance experts, but by the most senior leaders in the company (i.e., they should not be developed in a vacuum by regulatory or quality executives)
- Select effective leadership and organizational structure and align with the "Consent Decree First" culture
- Develop planning capabilities, processes and tools tailored towards the new reality
- Evaluate the impact to the core business, including the repercussions for customers and patients, and develop a clear strategy to mitigate negative outcomes through realistic timelines and ramp-up production schedules

By addressing these needs your company can mitigate the near-term disruptions caused by a Consent Decree and eventually emerge as a stronger, more compliant and quality conscious company well-positioned for long-term success. The key is to develop realistic plans and commitments, accept the situation for what it is and make the best of a very challenging environment.

In an effort to reduce the risk that a company may find itself in a Consent Decree business in the first place, it is important for companies to clearly understand where they are in terms of compliance with FDA regulatory requirements. Sometimes companies have a false sense of security that all is well after an FDA inspection finds limited or no adverse findings. It may be a wise choice to team with a professional services organization that can objectively evaluate the quality systems organization and processes and identify gaps in meeting regulatory requirements. These prevention measures can drive improved product quality and profitability and establish confidence that future FDA inspections and other audits will have successful outcomes.

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