



The Executive Guide to Contract and Chargeback Management:

How Pharmaceutical Manufacturers Smartly Automate to Strengthen Profitability



Introduction

Small and mid-sized pharmaceutical manufacturers are struggling to manage large group purchase organization (GPO) contracts, process heavy volumes of chargeback submissions and ensure pricing policies are fully compliant with regulatory requirements.

Indeed, they are experiencing escalating costs and risks as these demands outstrip the capabilities of their existing processes and systems.

As the complexity of GPO contracts and expectations of large wholesalers grow, manufacturers run the risk of lost market share and massive revenue leakage. According to IDC Research, manufacturers lose 4-5% of revenue annually due to inefficiencies in the reconciliation process.¹

And, as regulatory requirements become increasingly burdensome, they are vulnerable to compliance risks including multi-million dollar fines and litigation. The mounting number of costly lawsuits in recent years underscores this problem.

At present, many pharmaceutical (and medical device) manufacturers rely on manual systems – such as Excel and Access – to handle contracts and chargebacks. These approaches tend to be inaccurate, inefficient and labor intensive. As sales volumes increase, they threaten to undermine operational effectiveness and corporate profitability.

Manufacturers need more advanced systems if they are to gain full control over their operations, enhance efficiency and continue generating profitable growth in today's increasingly competitive life sciences markets.

Fortunately, there are smart and cost-effective solutions that match the needs of today's dynamic and growth-focused pharmaceutical manufacturers. Best practice firms have embraced automated Contract and Chargeback Management systems. This integrated solution is designed to:

- Enhance contract management
- Eliminate chargeback overpayments
- Reduce labor and operational costs
- Manage and mitigate compliance risks
- Strengthen negotiating leverage

Fast-growth firms have learned that the payoffs associated with this solution are clear and compelling. In a market where patent clocks are constantly ticking and margins are always at risk, automated Contract and Chargeback Management solutions represent an opportunity to maximize profitable growth while limiting operational and regulatory risk.

Market Trends and Drivers: Competition, Distribution and Regulation

Several pharmaceutical industry trends are now driving manufacturers to rethink their approaches to contract and chargeback management. Manufacturers are facing increasing competition for market

¹ Newmark, Eric, "Revenue Leakage: Plugging the Holes in the Pharmaceutical Channel," IDC Health Industry Insights, Jan. 2007.

share, increasing demands from big wholesalers and increasing risks and liabilities associated with government regulations.

Intensifying competition is linked to the large number of drugs now coming off patent and the subsequent introduction of new generic drugs. The next few years represent “a golden era for generic drugs, as patents begin to expire on brand-name medications with more than \$60 billion in combined annual sales,” according to the *New York Times*. “That will open the door to copycats that may be 30 percent to 80 percent cheaper.”²

The average cost to develop a new prescription drug is now \$897 million and the average cost of a biotech product is \$1.2 billion, according to reports by the Tufts Center for the Study of Drug Development (CSDD).³ Given the enormous costs associated with getting a drug to market in the first place, manufacturers with patented drugs are under severe pressure to maximize profitability while they retain patent protections. Generic manufacturers, by contrast, must operate in an extremely efficient manner to drive profitability with far lower margins.

Meanwhile, wholesaler demands on drug manufacturers have grown in recent years due to their enormous market leverage. The big three wholesalers – Cardinal Health, McKesson, AmersourceBergen – represent the only viable path to market for many manufacturers. As a result, the wholesalers tend to have enormous market power relative to small- and mid-sized manufacturers.

In recent years, these wholesalers have made growing demands of manufacturers in terms of automation. They expect manufacturers to process transactions using EDI. Unfortunately, many manufacturers lack the systems necessary to ensure such transactions are accurately managed.

Finally, manufacturers are under growing pressure associated with government regulation. The new Obama Administration has made it clear that it intends to take steps to reduce drug costs, setting the stage for regulatory changes in the months and years ahead. In addition to existing Sarbanes-Oxley requirements, manufacturers will be under severe pressure to ensure pricing is reported accurately to meet the regulatory requirements of the Centers for Medicare and Medicaid Service (CMS) as well as state health agencies.

Business Challenges: The Limits of Manual Approaches to Contract and Chargeback Management

Many small- and mid-sized manufacturers are still reliant on manual approaches for managing contracts and chargebacks. They depend on such tools as Microsoft Excel and Access to conduct complex transactions, calculations and reporting challenges.

While disparate spreadsheets may prove acceptable tools in the early days of an organization, manufacturers can quickly become overwhelmed by the demands that arise as sales grow. In the absence of automated and integrated solutions, today’s manufacturers are confronting an array of key business challenges. Among them:

² Saul, Stephanie, “More Generics Slow Rise in Drug Prices,” *New York Times*, Aug. 8, 2007.

³ Tufts Center for the Study of Drug Development, Press Release, May, 13, 2003, <http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=29>

- **Mishandling of contracts.** Due to the use of manual approaches, companies often mishandle their contracts, both direct (wholesalers, retailers, chains) and indirect (GPOs) GPO contacts, which can number in the hundreds, include frequent product and price changes. Memberships, which can range in the thousands, can change daily. Given these variables, contract management can be costly, time-consuming and prone to error. Such errors make it extremely difficult for manufacturers to validate chargebacks and management fees and rebates as well as report accurately on their activities.
- **Overpayment on chargebacks.** Given that chargeback credits can exceed millions of dollars per month and account for 15-20% of gross revenue on branded drugs and 2-4% for generics, manufacturers can severely undermine profitability through inaccurate and inefficient chargeback validation. Unfortunately, this is a common problem when wholesalers are submitting thousands of chargeback lines per day. The problem is that wholesalers are prone to misstate chargebacks for many reasons (see Appendix A: *Typical Chargeback Issues*). Overwhelmed manufacturers, who are incapable of rapidly and effectively validating chargeback submissions, are often likely to credit their wholesalers for inaccurate chargebacks and needlessly cut in to their own margins.
- **Excessive labor and operational costs.** Given the inefficient and ineffective nature of manual methods in the face of increasing volumes, manufacturers are liable to employ at least twice as many people in contract management positions than would be necessary in an automated environment. GPO contracts must be maintained, chargebacks validated and government reports produced. However, the potential for inaccuracies and slow, unproductive work is tremendous due to the heavy volumes of data that must be captured, calculated and acted upon using spreadsheets and other limited tools.
- **Vulnerability to legal and regulatory risks.** To meet the demands of CMS for price validation, manufacturers must report Average Manufacturer Price (AMP) and Wholesale Acquisition Cost (WAC) in a timely and consistent manner. To meet accounting requirements (linked to Sarbanes-Oxley), fees and rebates must also be accurately calculated, accrued and paid. However, it's difficult to conduct this reporting effectively and take the right action when appropriate systems for capturing and calculating data are not in place. Without accurate reporting, manufacturers run the risk of costly fines and litigation (see Appendix B: *Summary of Legal Actions*) or even government rulings that can put them out of business.
- **Weak negotiating leverage.** Considering the heavy concentration of the drug distribution business among the Big Three, small- and mid-sized manufacturers have relatively limited market leverage. As a result, wholesalers have a tendency to provide inaccurate chargeback data. Manufacturers, therefore, are likely to see their profit margins eroded if they cannot accurately and effectively validate chargebacks. Moreover, manufacturers are unable to renegotiate contracts in favorable ways if they cannot track the sales performance trends of individual wholesalers. The challenge for manufacturers revolves around holding wholesalers accountable for their performance. It's difficult to reach this objective, however, without automated systems to capture, calculate and report on critical data.

All of these challenges must be addressed if manufacturers are to maximize profitability. Each one these challenges undermines profitable growth directly or indirectly. If manufacturers are to thrive in today's intensely competitive markets, they must consider the solution that has already been adopted by best practice firms.

The Solution: Automated Contract and Chargeback Management

To enhance profitability in today's increasingly complex and competitive marketplace, small- and mid-sized pharmaceutical manufacturers are now implementing automated Contract and Chargeback Management solutions. These integrated systems bring high performance capabilities to companies that enable them to accurately, effectively and efficiently manage their contract and chargeback challenges.

Industry analysts and influencers see big promise in these solutions. "Companies make huge commitments in concessions made via contracts in hopes of generating increased sales," says AMR Research's Hussain Mooraj. "It is, therefore, important to raise the visibility of contract [and chargeback] management performance and implications across a broader part of the enterprise."⁴

These systems have multiple dimensions. Among them:

- **Contract Management.** Addressing both direct (wholesalers, retailers, chains) and indirect (GPOs) sales, systems should capture and handle an array of contract maintenance information. They should help manufacturers keep track of contract type/link to wholesaler, contract effective dates, GPO administration fees, wholesaler rebate percentages, product prices, effectivity dates, and price change history.
- **Chargeback Reconciliation.** By ensuring chargebacks are processed accurately and rapidly, smart systems raise operational performance levels and eliminate chargeback overpayments. Key capabilities should include validation (contract, price, membership, date, duplicates, tolerances), accruals for fees and rebates, and updates to accounts receivable.
- **EDI.** Recognizing that EDI capabilities are expected by wholesalers, systems should handle pricing (845), chargebacks (844), and dispute resolution (849).
- **Fee and Rebate Programs.** Systems should automatically calculate Medicare and Medicaid rebates as well as wholesaler rebates, while accruing for fees to contract holders. Automated accrual helps companies ensure they are not subject to fines and penalties related to Sarbanes-Oxley legislation.
- **Workflow.** To connect disparate departments and "link system events to human actions," smart systems should also incorporate workflow capabilities. They should be able to handle approvals and routings, alerts and notifications, and price/contract updates, changes and expirations
- **Analytics.** Given the necessity for performance measurements and Medicare/Medicaid reporting, systems should have advanced analytics and reporting capabilities. Business intelligence of this sort enables manufacturers to accurately calculate and report figures for AMP, Best Price and Net Price. Moreover, analytics enables manufacturers to track customer performance (sales and quantity by customer) and contract performance (sales and chargebacks by contract) as well as perform trend analysis (on both direct and indirect sales).

⁴ Mooraj, Hussain, AMR Research, "Contract Management: A Core Component of a Successful Sales Strategy," July 7, 2006.

The Benefits of Automated Contract and Chargeback Management

Taken together, these capabilities can produce some compelling benefits. The CEO of one manufacturer, Aurobindo, notes that its automated approach to “processing orders thru EDI and processing chargebacks ... has reduced our daily manual processing efforts by approximately 80%.” But there are other gains to be realized. As a result of automated and integrated solutions, small- and mid-sized manufacturers are able to:

- **Enhance contract management.** Best practice firms are now more accurately, effectively and efficiently managing their indirect and direct contracts. They have rapid access to the data necessary to perform calculations, process transactions and produce key reports.
- **Eliminate chargeback overpayments.** By automatically validating and processing chargebacks, manufacturers are eliminating the labor-intensive and error-prone activities that contributed to chargeback overpayments in the past.
- **Reduce labor and operational costs.** By eliminating manual and labor-intensive work, companies can reduce headcount in their contract management departments by 50% or more.
- **Manage and mitigate compliance risks.** By effectively validating and reporting on pricing, manufacturers meet key regulatory demands. Still other capabilities address concerns around Sarbanes-Oxley. Such efforts address vulnerabilities that could otherwise lead to fines, penalties and lawsuits.
- **Strengthen negotiating leverage.** Best practice firms have visibility into sales trends and contract performance that give them important leverage in the contract renegotiation process with wholesalers. By evaluating wholesaler performance (and recognizing wholesaler chargeback errors), manufacturers gain the leverage necessary to enhance their position and profitability.

Case in Point: RxElite

Idaho-based RxElite Holdings, Inc. is a high growth, specialty pharmaceutical company that develops, manufactures and markets generic prescription drug products in specialty generic markets. RxElite’s products include anesthesia drugs, sterile liquid dose drugs (including respiratory inhalation drugs, ophthalmics and injectable drugs) and transdermal patches.

RxElite has established distribution agreements with more than 90 percent of the U.S. generic drug market, including customers such as Wal-Mart, Walgreens, McKesson and Cardinal Health. In June of 2007, the company launched Sevoflurane, its primary anesthesia product. Sevoflurane is part of a product category that represents a \$400 million U.S. market, has only two competing products and high barriers to entry.

Challenges. Due to its exponential growth, RxElite needed a way to make its chargeback management process more efficient, automated and streamlined while minimizing revenue leakage and overpayments. “We were processing chargebacks with nonintegrated systems that included our accounting system, spreadsheets and a series of paper reports from our partners,” said RxElite’s Chief Operating Officer.

“The process was highly error-prone because of the volume of transactions we had to review manually. Also, the labor costs associated with managing chargebacks were becoming prohibitively high and impeding our ability to grow.”

At the same time, RxElite was facing increased pressure from both large and mid-tier wholesalers to accept and process chargeback submissions electronically. “Customers naturally expect us to make doing business as easy as possible,” he said. “And we recognized that our inability to accept and process chargebacks according to their directives was negatively impacting sales.”

RxElite also recognized that it had long ago outgrown its QuickBooks accounting system. The company’s plans to go public further heightened its need to implement an operational system of record designed specifically for the pharmaceutical industry—one that would enable the company to grow profitably.

But after months of research, RxElite struggled to find a software vendor that could offer an integrated ERP and chargeback solution. Finding a single integrated system was essential from both a timing and a cost perspective. Facing an aggressive product launch, and growth schedule as well as going public, RxElite couldn’t afford to go through a lengthy implementation process involving two major disparate systems.

“There were also cost considerations,” said the COO. “The total costs of two separate systems would have topped \$1 million, and integrating the two applications would have required tremendous effort and an additional investment of at least \$100,000.”

Solution. RxElite selected CDC Software’s ERP system, the only fully integrated ERP and chargeback/contract management solution in the market specifically tailored for manufacturers in the life sciences industry.

The solution leverages its backend capabilities around pricing, promotions, chargebacks, rebates and discounts in its ERP system—as well as its sales order, inventory and EDI capabilities—and marries them with a cost-effective chargeback and contracts management application, all in one single system.

The Contract and Chargebacks Management functionality in the solution supports:

- Contract maintenance for direct (retail chains) and indirect (GPOs)
- Electronic processing of chargeback submissions/disputes and price changes
- Validation of chargeback against contract and memberships
- Real-time calculation of administrative fees and rebates
- Real-time accrual of chargeback values to the General Ledger
- Calculations for average manufacturer price (AMP) and wholesale acquisition cost (WAC) to meet the Deficit Reduction Act (DRA) Final Ruling guidelines

Results. According to the firm’s COO, not only was CDC the most cost effective solution, it also enabled RxElite to drastically shorten time to results. “By going with this fully integrated CDC solution, we have saved hundreds of thousands of dollars and 9 months of implementation time,” he said. “The cost savings have come from not just direct labor costs, but also from our ability to prevent erroneous deductions.”

By fully automating the contract maintenance and chargeback process, the integrated CDC solution has enabled RxElite to reduce the time and costs spent reviewing, validating and processing chargeback submissions from several hours—even days—to only a few minutes. Accuracy on contract pricing and transaction dating has also improved, further reducing chargeback processing times.

The company's ability to accept chargeback requests via EDI also means that it can more efficiently manage errors in chargeback submissions from customers. When errors are identified, CDC's EDI-driven dispute mechanism is automatically triggered, generating the necessary supporting documentation for reasons of rejection, and further reducing the need for costly manual intervention.

Through CDC's EPM Sales reporting tool, RxElite can now easily calculate administrative fees associated with chargebacks and provide accurate reports of those fees directly to customers. "The standardized, EDI-based nature of these reports gives our customers a much greater sense of security and accuracy than our previous spreadsheet-based approach," commented the COO. EPM Sales also generates real-time running totals of chargeback quantities to support chargeback dollars being requested. This helps RxElite minimize the risk of overpayment on submissions.

"Being able to run these reports in a timely fashion is not only critical to ensuring that we're meeting and fulfilling the obligations of the contract, it has also allowed us to further improve our relationships with our customers," he added. "Customers appreciate the new level of accuracy, our efficiency in processing requests and the fact that we now have official documentation that can be easily tracked—not just spreadsheets or handwritten records."

Moreover, by being able to accept and process large-volume chargeback submissions via EDI, RxElite has been able to cut costs and pursue new business opportunities. "In the past, going after new prospective customers or pursuing additional business with existing customers would have entailed hiring more internal resources to handle what was then a very labor intensive chargeback and contract management process," concluded the COO. "The software platform has enabled us to position ourselves for growth."

Decision Criteria: What to Look for in a Contract and Chargeback Management Solution Provider

Pharmaceutical firms exploring a Contract and Chargeback Management solution that addresses their operational challenges should consider some of the key criteria that have guided other firms that have successfully made such investments. Among them:

- **Integrated Solution.** Expect an offering that packages contract, chargeback and order management as well as reporting and analytics as a single, unified and integrated solution. Such integration helps ensure a rapid and cost-effective implementation. You should not have to integrate separate modules and capabilities – a challenge that adds cost and lengthens implementations.
- **Full ERP Integration.** Look for a solution provider that can also address manufacturing, cGMP compliance, inventory and lot traceability challenges. Should further integration with manufacturing and logistics be necessary, your solution provider should have deep ERP capabilities.
- **Life Sciences Expertise.** Whether you are a pharmaceutical or medical device/equipment manufacturer, expect your solution provider to have deep experience in the life sciences industry and expertise dealing with the particular challenges and regulations that emerge in this sector.

- **SME Focus.** Small- and mid-sized enterprises often run the risk of being financially and organizationally overwhelmed when they work with vendors who are optimized to work with large companies. Look for solution providers that specialize in working with SMEs and have adapted their offerings to your objectives and budget. The solution shouldn't require an army of consultants and an endless timeline to implement.
- **Referenceable Clients.** Expect your solution provider to provide a wide array of successful clients in the life sciences sector – companies that have faced challenges that match your own.

Today's Contract and Chargeback Management systems offer the potential to dramatically enhance operational performance, address compliance risks and strengthen profitability in markets that are intensely competitive. As best practice firms have realized, decision criteria such as these can help ensure one is investing for maximum returns and success.

Appendix A - Typical Chargeback Issues

Chargebacks can be misstated for a number of reasons.⁵ Among them:

- **Returns to wholesalers** – wholesaler issues a credit to the Prime Vendor without issuing a corresponding negative chargeback to the pharmaceutical company.
- **Resales of returned products** – wholesaler claims a second chargeback upon the resale of product previously returned
- **Sales by wholesalers of alternative sourced product** – wholesaler inappropriately claims a chargeback when it sells a product not acquired directly from the pharmaceutical company.
- **Chargeback processing errors** – for example, claiming a chargeback at rates different than the contract or for: products that were not shipped to the claimed customer
- **Prime Vendor not a member of buying group** – chargeback customer is not eligible to purchase off of the buying group contract
- **Contract invalid or expired** – contract assigned to chargeback is not valid or has expired
- **Incorrect contract pricing** – chargeback price does not agree to contract
- **Duplicate chargeback request** – chargeback included in current submission twice
- **Incorrect WAC Pricing** – wholesaler purchase price included in chargeback is not the original price the wholesaler paid

Source: PriceWaterhouseCoopers

Appendix B - Summary of Legal Actions

- TAP: \$875 million fine for kickbacks and encouraging the reimbursement of samples
- Bayer: \$257 million for the sale of relabeled product to an HMO
- GSK: \$87 million for the sale of relabeled product to an HMO
- Warner-Lambert (Pfizer): \$39 million for misreporting Best Price
- Astra-Zeneca: \$355 million for encouraging the reimbursement of samples
- Abbott: Has set aside \$622 million regarding Ross enteral nutrition products
- King Pharma: \$124 million for failing to accurately report the average manufacturer price and best price for its Medicaid-reimbursed drugs between 1994 and 2002
- MN, TX, NV lawsuits against manufacturers regarding AWP
- House Energy and Commerce Committee letters to 26 companies regarding AWP, AMP
- Schering-Plough fined \$345 million for fraud issues.
- Schering-Plough fined \$435 million for anti-kickback, fraud issues
- BMS penalized \$499 million for its drug pricing, and sales and marketing activities

Source: CDC Software

⁵ PricewaterhouseCoopers, “Pharmaceutical Pricing Explained,” June 8, 2003.

About CDC Software

CDC Software, The Customer-Driven Company™, is a provider of enterprise software applications designed to help organizations deliver a superior customer experience while increasing efficiencies and profitability. CDC Software's product suite includes: CDC Factory (manufacturing operations management), Ross ERP (enterprise resource planning) and SCM (supply chain management), CDC Supply Chain (supply chain management, warehouse management and order management), e-M-POWER (discrete manufacturing) Pivotal CRM and Saratoga CRM (customer relationship management), CDC MarketFirst (marketing automation and lead management), Respond (customer complaint and feedback management), c360 CRM add-on products, industry solutions and development tools for the Microsoft Dynamics CRM platform, Platinum HRM (human resources), and business analytics solutions.

These industry-specific solutions are used by customers worldwide within the manufacturing, industries. The company completes its offerings with a full continuum of services that span the life cycle of technology and software applications, including implementation, project consulting, outsourced business services, application management and offshore development. For more information, please visit www.cdcsoftware.com.

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