

# Managing Contract Manufacturing for Life Sciences Industry using Enterprise Blockchain technology

## CHALLENGES

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Lack of visibility into contract manufacturing operations, mismatch in inventory data, and low confidence in quality processes

While Indian pharmaceutical industry is growing at a CAGR of ~22.4%, and with the impetus of COVID-19 likely to grow even faster, there is a need to improve operations to be able to effectively scale-up.

Life Sciences industry leverages a large number of Contract Manufacturing Organisations (CMOs) to manufacture starting materials, Active Pharmaceutical Ingredients (API), and formulations. A typical \$2B revenue firm engages >100 CMOs, and Big Pharma firms employ >1000 CMOs globally. CMOs enter into two agreements with their customers (typically referred to as Principals):

### SUPPLY AGREEMENT

Defines quantity, date of delivery, and logistics.

### QUALITY AGREEMENT

Defines all procedures to be followed for manufacturing, packaging, and logistics as per FDA and GMP guidelines.

## PROBLEM STATEMENT

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Execution of Supply and Quality Agreements requires constant cooperation and collaboration between the Principal and the CMOs.

Presently these agreements are manually executed (over email, phone calls, site visits, weekly review meetings, etc.), and as a result these inefficiencies that lead to the challenges described above.

## CLIENTS

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Life Sciences Corporations

## PRINCIPALS IN PHARMA INDUSTRY

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Contract Manufacturing Organisations (CMOs) manufacture starting materials, Active Pharmaceutical Ingredients (API), and formulations.



Typical Revenue: \$2B



Revenue (greater than) > \$2B

## SOLUTION

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Schrocken built Mosymphony to address these problems. It helps implement Supply and Quality Agreements at granular transaction level. All inventory, manufacturing, and quality transactions at the Principal or CMO are captured and made visible to the partner.

This provides unprecedented visibility to both parties into operations, and thus eliminates the need for manual processes, including reconciliation of inventory, manufacturing, and quality data.

## PILOT SETUP

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A pilot project was set-up to integrate the Principal with 2 CMOs for a period of 6 months.

Schrocken started with one CMO, and deployed two teams. One team was deployed at the Principal's Head Office, and another at the CMO site. This helped us engage the stakeholders, understand their response to the new solution, and mitigate their concerns about "change".

Unfortunately, with the sudden and unexpected advent of COVID-19, we haven't deployed the solution to the 2nd CMO, although we expect to start with the 2nd CMO in August 2020.

## RESULT

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The software was provisioned to both Principal and the CMO successfully. So far, more than 40 batches have been processed with this software (that's a significant number in the Life Sciences manufacturing).

The Contract Management Services (CMS) team at the Principal has now access to real-time inventory, manufacturing and quality information. This eliminated 80% of the manual communications and "synch-ups", improved ability to release the batches remotely, and improved sales and distribution planning leading to increase in service levels by 2% for the product.

The Principal is now planning to deploy Mosymphony at scale to its entire suite of 50+ CMOs.

## OUTLOOK

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The Principal we worked with is in the Top 10 Life Sciences corporations in India. The bigger corporations, globally, have the same set of problems, at a larger scale. Mosymphony helps dramatically improve collaboration between Principals and CMOs, generating even more concrete and impactful outcomes.

- ▼ **80%**  
Elimination of Manual Processes
- ▲ **2%**  
Improvement in Service Levels
- ▲ **50%**  
Batches can now be released remotely as against Nil earlier

## OBJECTIVES

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- + Supply and Quality Agreements are enforced without manual intervention
- + Elimination of Reconciliation by improving Process Standardisation, leading to Data Integrity
- + SOPs for on-boarding, training and stabilisation of new CMOs at scale

## THE CMO CONSISTENTLY UPLOADED THE FOLLOWING OPERATIONAL DETAILS

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- + Availability of Raw and Packaging Material
- + Batch Schedules
  - Batch Execution Details and Documentation
  - Batch Manufacturing Records (BMR)
  - Batch Packaging Records (BPR)
  - Certificates of Analysis (CoA)
  - Reconciliation Sheet
  - Shipping Documents
- + GRN of Raw Material made available by the Principal

Please visit us at [schrocken.com](https://schrocken.com), or write to us at [hello@schrocken.com](mailto:hello@schrocken.com) to learn how Mosymphony can revolutionise your CMO management capability in just 6 weeks.