11 Tips on Supply Chain Management Post Covid

Global Pharmaceuticals

WITH DALTON

Peter Pekos

Company Vision

"To make the impossible possible, Dalton Pharma Services uses its scientific and pharmaceutical expertise to bring customer ideas to life. We develop their new drug products, optimize the synthesis of therapeutic candidates, and manufacture them at the highest level of quality."

Disclaimer

This technical report is intended to provide information to quality and regulatory correspondents on some of the approaches that companies can take to circumvent challenges against supply chain issues in pharmaceutical industries. This technical report should be read in conjunction with the relevant laws, regulations, and guidance's that apply to your situation.

FDA inspected, HC approved, & MRA with EMA

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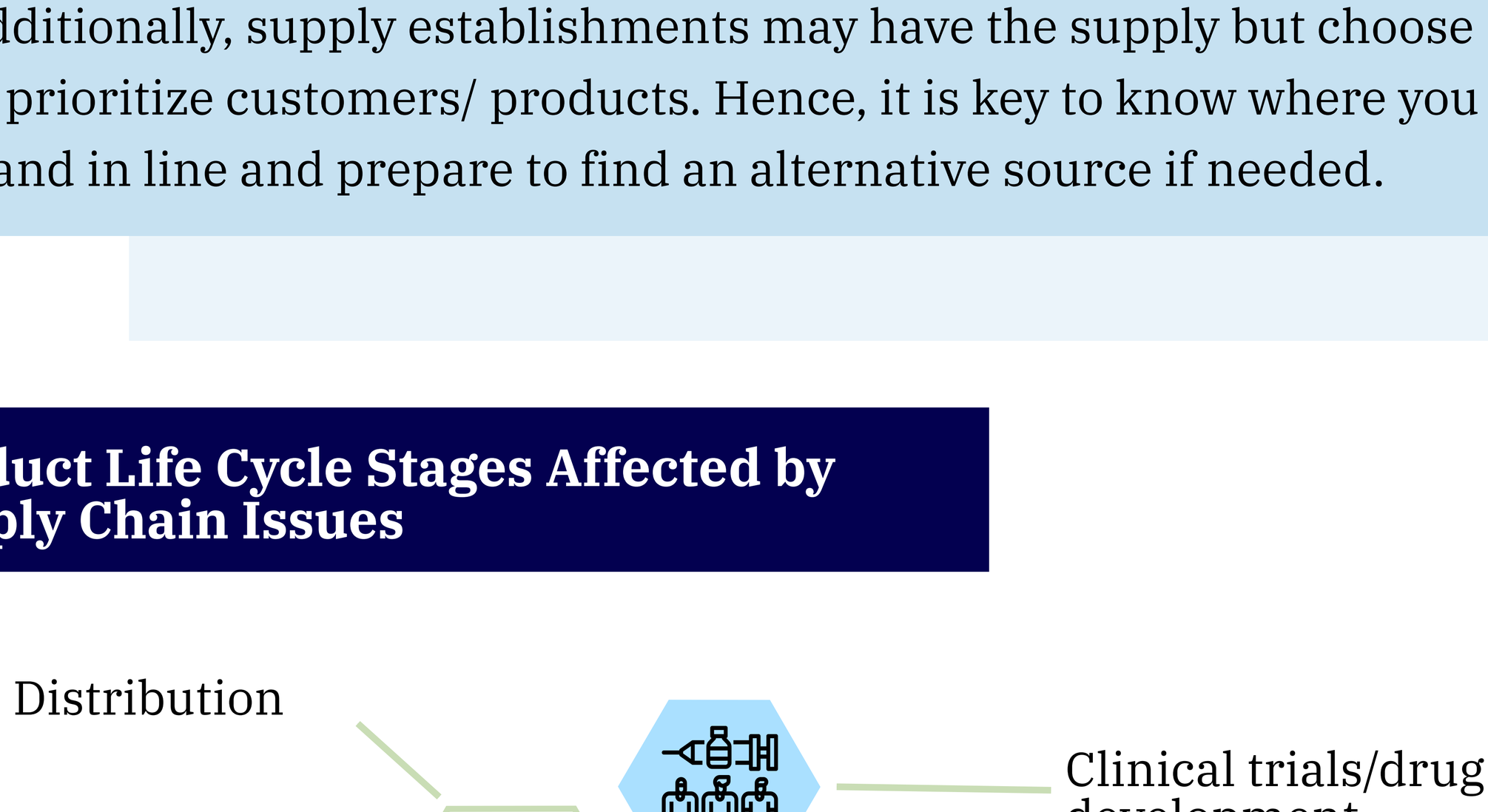
Intro

The COVID-19 pandemic created an unprecedented strain on the global health care system and led to an urgent need for access to health products. However, the scarcity of alternative supplies and materials, put a burden on pharmaceutical companies.

But why is there a scarcity of alternative supplies? Most, if not all, supply chains are set up primarily for cost efficiency and not resiliency or agility. This approach, along with limited local production capacity and export limitations on active pharmaceutical ingredients (API) or over-the-counter medication causes significant impact to the health care system. Hence, supply chain management is a crucial part of business strategy. Improving supplier coordination and communication is critical to achieving alignment, boosting supplier capacity, increasing profitability, and expanding medicine availability.

Additionally, supply establishments may have the supply but choose to prioritize customers/ products. Hence, it is key to know where you stand in line and prepare to find an alternative source if needed.

Product Life Cycle Stages Affected by Supply Chain Issues



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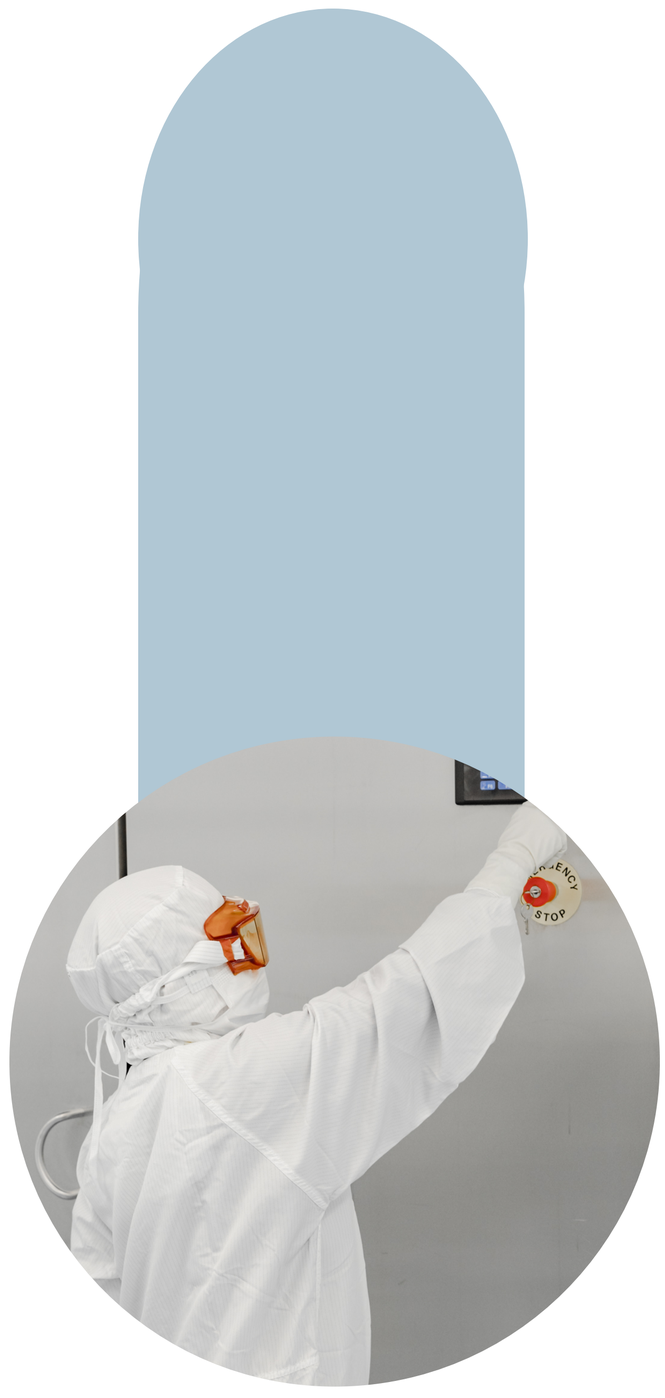
Business Strategies to Address Supply Chain Issues

1

Implement an Effective Pharmaceutical Quality System (PQS) at Your Facility

A successful PQS proactively focuses on performance, particularly through managing changes and continual improvements, as well as eliminating quality concerns that lead to complaints, shortages, and quality-related adverse events. In an effective PQS, manufacturers take ownership to set organizational objectives that drive quality, focus on innovation and continuous improvement, and use risk management to assure a dependable pharmaceutical supply. This involves identifying areas in the supply chain where supply may be vulnerable and addressing those vulnerabilities before shortages occur.



2

Understand the Importance of End-To-End Visibility

End-to-end visibility across production and supply is critical for capacity repurposing. This will necessitate the involvement of multiple external stakeholders and partners to pinpoint where gaps in supply chain may start and what effect they will have at each stage of production. Obtaining an overview of this will help understand key points of concern and allow you to strataegically allocate your resources to the most prominent issues of supply.

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3

Continually Assess Regulatory Capacities

Innovative and flexible regulatory measures have been implemented as part of the government's response to the pandemic. These measures have expedited the regulatory review of COVID-19 health products without jeopardizing their safety, efficacy, and quality standards. It is beneficial to stay up to date with policy updates in the case that regulatory flexibilities are introduced to alleviate supply chain shortages for non-Covid 19 products. For instance, in Canada, since 2017, drugs in or at risk of Tier 3 shortages may be eligible for exceptional importation and sale. Health Canada provides a list of "designated drugs" that are eligible for exceptional importation and sale as per sections C.10.004 to C.10.011 of the Food and Drug Regulations (FDR) in the case of drug shortages. This list is incorporated by reference in the FDR and is maintained regularly by Health Canada. Also be on the lookout for relevant guidance documents, such as Health Canada's Drug shortages regulations and guidance.

4

Use Alternatives Where Legislation Permits

Have prepared documentation that supports the safe use of the designated alternative drug, such as:

- The name of the product and the reason it's being used
- The differences between the products (i.e., approved indications, expression of strength, packaging, volume, concentration, storage conditions)
- The specific recommendations to health care providers about the product's appropriate usage (i.e., use during pregnancy)

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5

Understand Supplier Capability

It is critical to understand supplier capacity and limitations in delivering materials on time. Material planning should take into account the pending purchase orders, the stock in transit (both domestic and imported), and the available stocks in the vendor-managed inventories.

- Find alternate sources for the materials if the regular sources do not work
- Review all procurement and service contracts and update them if required
- For uninterrupted production, initiate emergency procurement plans with due approvals

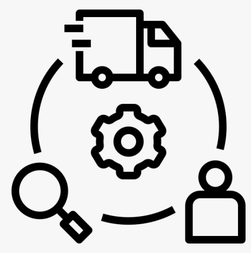
6

Diversify Your Supply Base

As opposed to having a single factory, supplier, or region to source supplies, allocate more sources in locations not vulnerable to the same risks.

7

Form a Strategic Task Force for Supply Chain



Decision-makers can form a dedicated Strategic Task Force (STF) to assess the current state of operations. The STF should comprise of cross-functional team members including sourcing and procurement, manufacturing, distribution, after-sales support, regulatory, etc. Based on the priority of these functions/areas and their impact on the overall supply chain, cross-functional team members should draft a list of action items.

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8

Digitalization of the Supply Chain

Invest in supply chain management systems that will provide greater efficiency and accuracy, rather than relying on spreadsheets and manual processes.

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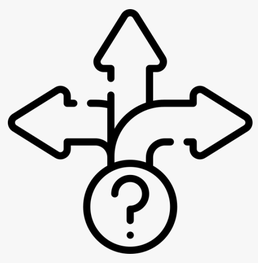
Establish Clear and Transparent Decision-Making Processes

Visibility with all team members on all supply related decisions will help avoid miscommunication that can lead to supply disruption. Descision makes must demonstrate product and process knowledge and extensive manufacturing experience.



10

Be Proactive, Not Reactive

Predict the market demands post-COVID-19 by analyzing the general demand pattern including emergency requirements across the network. With this data, identify key components subject to supply disrubtion and establish a 2 year safety stock for it which will provide you with a buffer period.

11

Participate In International Harmonization and Regulatory Convergence

Engage with the development of international regulatory collaboration to obtain insight into their practices and adopt any suitable mechanisms to strengthen your business' regulatory capacities.

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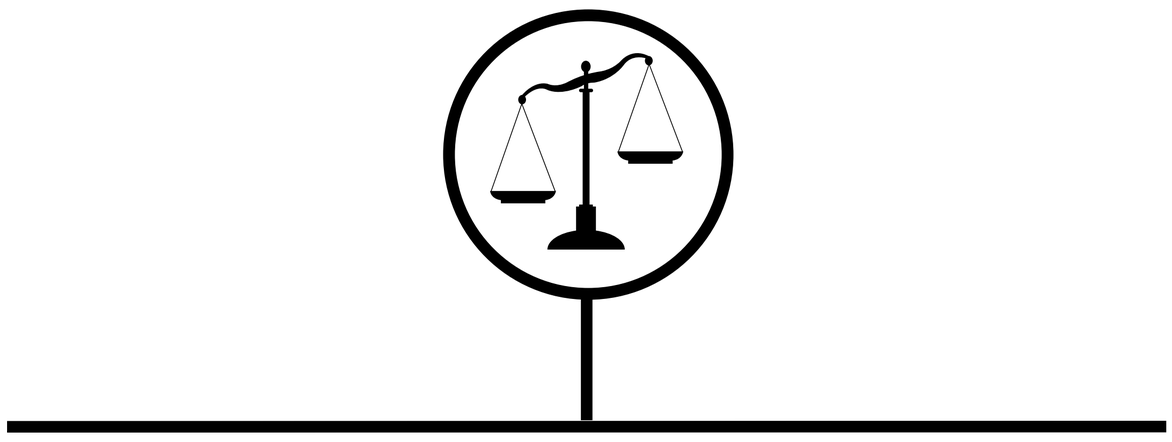
International Regulatory Response to Critical Product Shortages

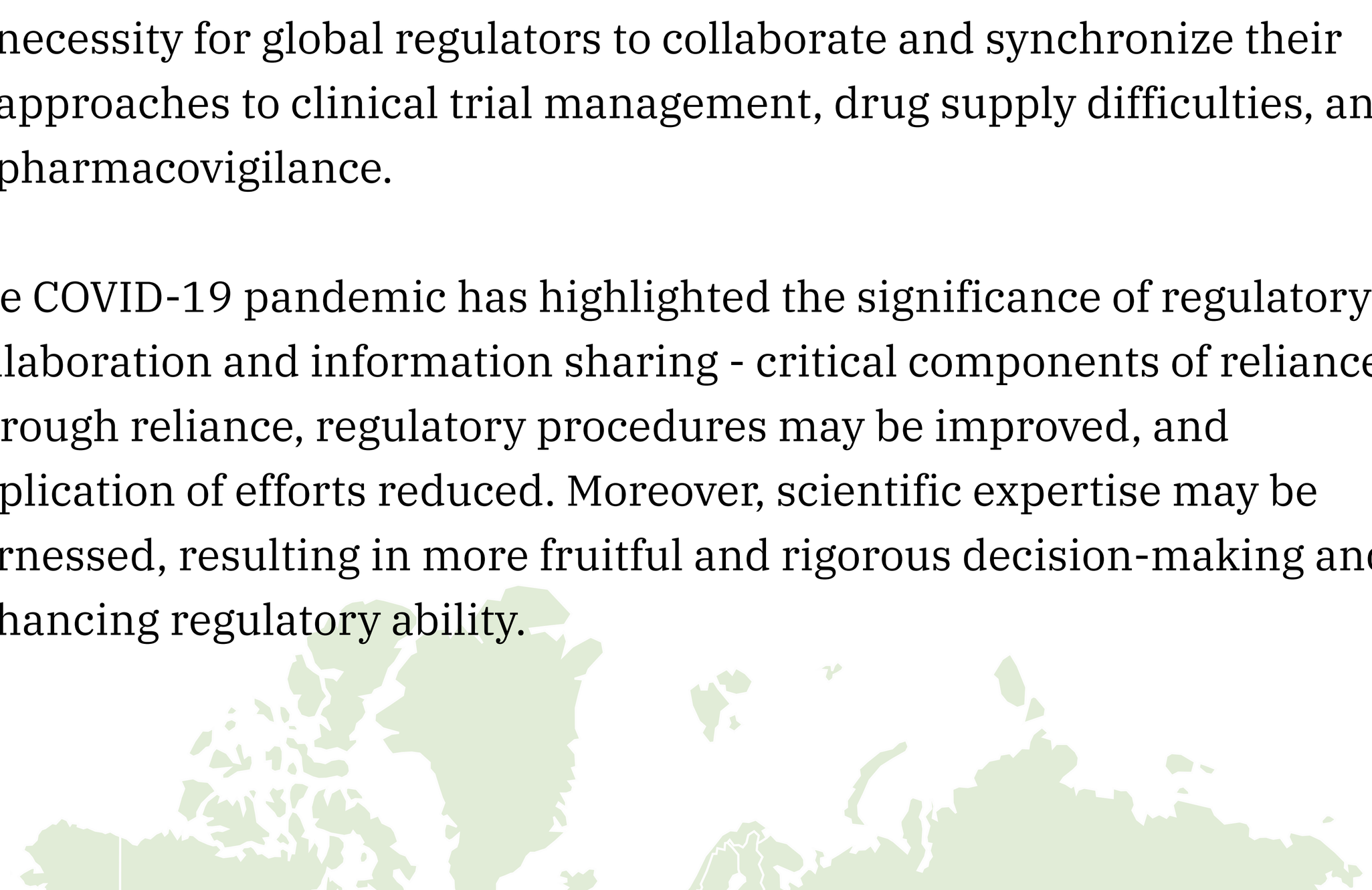


Global

The International Coalition of Medicines Regulatory Authorities (ICMRA) is an advocacy entity of regulatory authorities that collaborate to address global regulatory pharmaceutical challenges.

- On 14 May 2020, the International Coalition of Medicines Regulatory Authorities hosted a virtual conference of regulators from around the world to address high-level policy concerns and regulatory needs in response to the current COVID-19 pandemic. In light of the medical urgency posed by COVID-19, the strategy discussion emphasized the necessity for global regulators to collaborate and synchronize their approaches to clinical trial management, drug supply difficulties, and pharmacovigilance.

The COVID-19 pandemic has highlighted the significance of regulatory collaboration and information sharing - critical components of reliance. Through reliance, regulatory procedures may be improved, and duplication of efforts reduced. Moreover, scientific expertise may be harnessed, resulting in more fruitful and rigorous decision-making and enhancing regulatory ability.



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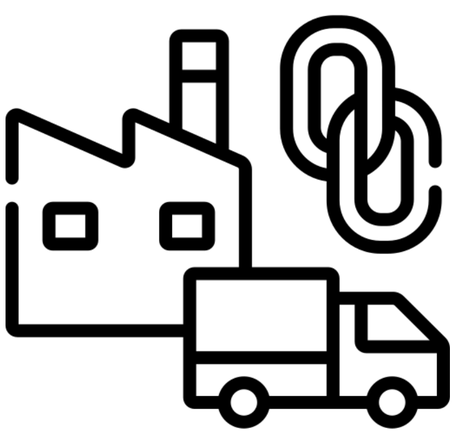
Dalton's *Services*

We bring over 35 years of experience developing products for our clients that are compliant, transferable, and scalable.

Dalton is a leader in the development and manufacturing of complex cGMP APIs. Our skilled scientists can support your drug discovery process through API Synthesis for all stages of pre-clinical and clinical trials as well as small scale commercial manufacturing. We provide integrated process development, API manufacturing and finished dose manufacturing at a single location with the expertise required for developing a process that is robust, transferable, and scalable to meet your requirements.

Our API development services include:

- Lead identification
- Synthetic route development
- Feasibility studies & tech transfer
- Process optimization & scale-up
- Scale-up troubleshooting
- Engineering batches
- cGMP API manufacturing



Dalton is Health Canada licensed to manufacture, test, and package complex pharmaceutical products for global markets. US FDA inspected; Dalton manufactures commercial products for the USA. The MRA (Mutual Recognition Agreement), recognizes Health Canada Licensed facilities in seven countries.

For more information on services we provide, visit our website.

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