



DRONE TECHNOLOGY – FUTURE OF SUPPLY CHAIN - QUALITY AND COMPLIANCE WHILE DELIVERING MEDICINES THROUGH “DRONES”



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Introduction

Quality and compliance are two critical aspects of the Pharmaceutical Industry. If we cannot deliver either of them, then we risk the health and safety of the patients. One of the key components that we shall evaluate in this point of view (PoV) is ensuring the quality and compliance of medicines while delivering through drones.

The biggest challenge in an existing mode of medicines delivery

is about the “Quality”, “Safety” and “Compliance”, as at times it might take from a few days to weeks for the delivery of medicines based on urban environments and geographical location. This challenge becomes multi-folded during emergencies such as natural disasters (floods, tsunamis, lockdowns, earthquakes, wars, etc). One of the solutions to this challenge would be the use of Uncrewed Aerial Vehicles (UAV) or drones.

Various Laws/Regulations governing drones

	USA	EU	India
Regulations	<ul style="list-style-type: none"> • 14 CFR Part 21 • 14 CFR Part 107 Federal Aviation Administration (FAA) classification of drones (Based on weight) • 14 CFR Part 135 • Low Altitude Authorization and Notification Capability (LAANC) • National Air System (NAS) for controlled and uncontrolled zone 	<ul style="list-style-type: none"> • 2019/945 • 2019/947 	<ul style="list-style-type: none"> • Drone Rules, 2021 • Drone (Amendment) Rules, 2021 • Directorate General of Civil Aviation (DGCA) “Unique Identification Number is issued by DGCA for Drones” • Indian Council of Medical Research (ICMR)
Certifications	<ul style="list-style-type: none"> • Type certification from the Aircraft Certification Office (ACO) that covers the design of the aircraft and its parts • Production certification to manufacture duplicate products conforming to approved designs • Airworthiness certification is necessary for safe operations 	<ul style="list-style-type: none"> • Type certification • Airworthiness • Pilot certification 	<ul style="list-style-type: none"> • Type Certificate (TC) for Drone
Category	Based on the weight a drone carries, operating altitude, and operating speed	Based on a risk-based approach Type 1 – Low risk Type 2 – Medium risk Type 3 – High risk	Airplane - remotely piloted aircraft system Rotorcraft - model remotely piloted aircraft system Hybrid unmanned aircraft system - autonomous unmanned aircraft system

Additional permissions required in India for using Drones:

In general, the process for receiving commercial clearance to fly an RPAS in India is quite complex, requiring applications and interactions with multiple agencies as below:

Directorate General of Civil Aviation	Import clearance Issuance of UIN post registration on the DigitalSky Platform Issuance & Renewal of UAOP Suspension/Cancellation of UIN & UAOP in case of violations of regulations
Directorate General of Foreign Trade	Import license
Ministry of Home Affairs	Security clearance
Ministry of Defense	Air defense clearance Monitoring of RPA movements in the country
Wireless Planning and Coordination Wing, DoT	Equipment Type Approval (ETA) or License for RPA
Bureau of Civil Aviation Security	Approval of the Security Program
Airport Authority of India	Flight Plan Approval Monitoring of RPA movements in the country
Local Police Office	Enforcement of violators as per applicable IPCs
DigitalSky Platform Registration (Controlled by DGCA)	Registration is Mandatory for all UAVs to Obtain UIN to start flying operations

Packaging of Medicines/Drugs

The need for packaging of medicines/drugs is mainly governed by Container Closure Systems for Packaging Human Drugs and Biologics-Chemistry, Food and Drug Administration, May 1999. This guidance concentrates on packaging requirements and the stability of drugs during transportation. For India, ICMR has come up with packaging guidelines for medications and vaccines through drones.

Challenges about drones and products being shipped through drones

Drones could have multiple challenges in terms of their security (Hijacking), safety (Social Issues like theft), multiple regulations, high insurance cost, Identification of the exact location of delivery, unsuccessful deliveries, failures due to malfunction, battery drain, and technical glitches.

Whereas challenges for products being shipped through drones could be temperature control shipment, unexpected climate changes, maintaining the aseptic conditions, unwanted situations like drone theft, damaging of materials, pre- and post-delivery quality of material, increased supply chain cost, and high insurance cost.



Future of Commercial Operations

Current restrictions on operating drones within line of sight must improve to make commercial operations successful. To get economic benefits out of drone operations, the drones must travel BVLOS (Beyond Visual Line of Sight) in autonomous mode. As the desire to work with the drone to deliver medicines has increased over the past decade; many trials/proofs of concept studies are taking place across the globe to make this

situation a reality. These trials/proof of concept studies will become the basis for healthcare authorities to come up with standard processes and regulations for using drones for medical purposes. However, to sustain commercial drone operations for the medicine delivery market, businesses need to locally own and operate a drone-supported system and integrate then within their current supply chain system.

Quality and Compliance requirements for using drones for medicines delivery

Medicine delivery using drones have remarkable importance for delivering high-cost, low stable, stringent storage condition medicines (like Vaccines). Quality and compliance for such services could be ensured as follows:

Weight of substance/product to be assessed based on drone capacity for delivery

Pre and post quality control testing of drugs/medicines

Assessment of storage conditions inside the drone where the material will be kept for shipping

Assessment of safety conditions inside drone while carrying materials

Risk assessment of safety of substance/product and environment in case of accidents

Process steps:

1. Understand the substance/product planned to be shipped
2. Assess and assign the weight of the material/package to be shipped as per the capacity of the drone
3. Collect historical data on material, drones, and environmental condition
4. Develop a hypothesis for risk-based quality and compliance for shipment (Refer [R17] for risk assessment for the use of drones)
5. Agree on all the parameters as per the standards/regulations below:
 - a. The Federal Aviation Administration (FAA) rules for small unmanned aircraft systems (UAS), or “drones,” highlights of the rule, 14 CFR Part 107
 - b. Quality and compliance as per Medical Devices Directive 93/42 EC
 - c. Country and state regulations
6. Design an algorithm to predict the packaging requirement, shipping conditions monitoring, and quality control checks (pre- and post-shipment)
7. Validate the outcome
8. Refine the algorithm and re-validate the same until the outcome is acceptable
9. Baseline the algorithm and create an analytical model to evaluate the stability and safety of medicines/lifesaving products
10. Design and develop a technological tool for data acquisition, analysis, storage, and visualization.

Infosys Consulting (LS) capability in this area

1. We can design, and guide drone algorithm regulations, feed the data, collect the business rules, and put them in a system
2. Based on the data gathered and generated, we can assess the limitations, understand the system, or model the system and start churning out the analysis ourselves
3. Can create conclusions based on our SME knowledge and guidance understanding
4. Can create a repository for document flow and its safe archiving

Challenges in solution design

1. Data quality of existing shipments
2. Unanticipated changes in environment/regulatory guidelines
3. Variable stress conditions from the outside environment to drone
4. Impact of drone hardware failure
5. Supply chain, packaging, and containment challenges

Conclusion

The key to success is to conduct the quality and compliance assessment of the shipment of drugs/medicines logically and to plan and design an efficient process, that shall produce a robust model for the shipment of pharmaceutical/biopharmaceutical products using drones.



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About the Authors



Sangita Goyal

Principal Consultant, IC LS

Sangita has around 18 years of professional experience working in the areas of Project Management, Quality Management (QC/QA/Regulatory), requirement Elicitation, Process analysis and testing's, R&D consulting to speed innovation, Quality, and Audit management, worked for leading Pharmaceutical companies.



I.V. Srinivasa Reddy

Senior Consultant, IC LS

Srinivas has around 13 + years of professional experience in the area of Clinical trials, Pharmacovigilance, Regulatory Affairs, Project Management, Business Analysis, Automation, Quality Management, Audits & Inspection supporting top 20 life sciences and healthcare organizations.



Vengatesan Perumal

Senior Consultant, IC LS

Vengatesan is an experienced consultant with the Life Sciences practice supporting a large pharma engagement. He has 6+ years of experience in program management, automation, and process optimization with expertise in the Business Intelligence domain.



Abhishek Singh

Analyst, ICLS

Abhishek is a Business Analyst with the Life Sciences practice. He has 6+ years of experience and comes from a Pharmaceutical Background with experience in Pharmaceutical Sales and Marketing, Digital Transformation, and Brand Management. As an Analyst, He has worked on Analytics Projects.

For more information, contact askus@infosys.com



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