SUPPLIER VERIFICATION AND RISK MANAGEMENT

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NEWS 1

DRUG REGULATION

Mumbai's JJ Hospital to The Gambia: 36 years apart but a familiar story of deadly toxic drugs

Fourteen people died after being administered adulterated glycerine in 1986. The case against the commercial entities involved is still underway.

Tabassum Barnagarwala
Nov 11, 2022 · 09:00 am

Plea for Rs. 1 lakh compensation

JJ PROBE

The cure that killed

Reveal report

Reveal Lentin report, say victims' families

By Rupa Chinai and Quaid Najmi

BOMBAY, Jan. 24.

On January 25, two years ago, patients in the State Government-run J.J. Hospital in Bombay were "dying like flies". On this day, the

mission of Inquiry, probing into the cause of these deaths, and the state of the public health system in Maharashtra. They pinned their hopes on Mr. Justice Lentin's report, which was delivered to the Maharashtra Chief Minister on November 30th.

with money. Severe steps must be taken against the offenders. They should be publicly flogged. This is the only way such incidents can be prevented from recurring", he said.

Insisting on anonymity, as he feared repurcussions for holding such

is a situation of corruption. Unfortunately we have to accept this as our fate. Immorality has gone into the Indian bloodstream, everywhere people are being looted. The death of these 14 people is meaningless, it is no use trying to create public opinion", he said, struggling to con-

NEWS 2

Whatever happened to the case of 66 child deaths linked to cough syrup from India?

August 31, 2023 · 4:13 PM ET

By Kamala Thiagarajan

Mariama Kuyateh, 30, holds up a picture of her son Musa, whose death from acute kidney failure on Oct. 10 was linked to contaminated cough syrup imported to Gambia, where they live, from India. The World Health Organization issued an alert about the medication.

NEWS 3

News | Health

Indonesia court hearing into children killed by toxic cough syrup

Some 200 children have died of acute kidney injury in Indonesia since last year and dozens of cases linked to cough syrup have been reported in The Gambia and Uzbekistan.

Safitri Puspa, 42, the mother of an acute kidney injury victim, wears a T-shirt depicting her son Panghegar Bhumi, 8, as she attends a preliminary hearing for a class-action lawsuit filed against the Indonesian government and drug companies for allowing the sale of tainted cough syrup in Jakarta, Indonesia, on January 17, 2023 [Ajeng Dinar Ulfiana/Reuters]

Mortal Consequences of wrong excipient Procurement

While manufacturing drug formulations for human use we are normally very cautious about buying high quality APIs.

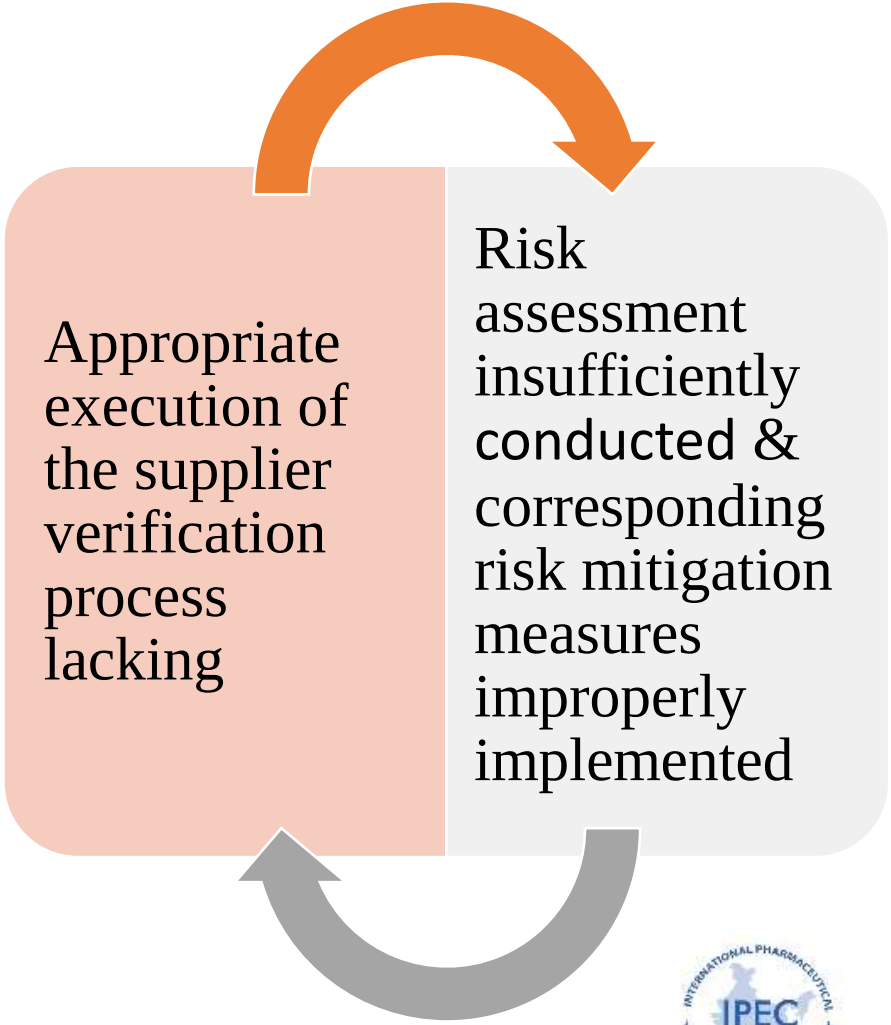
And we rarely hear any untoward incident due to use of these APIs.

Then why we hear these fatal consequences?

This is due to low quality or sub standards excipients?

How to overcome these challenges causing such fatal damages

- Its high time that we learn from such incidents.
- Let us understand the reasons behind these tragic episodes-
- And how by working on two major grounds which can be considered to avoid such happenings.



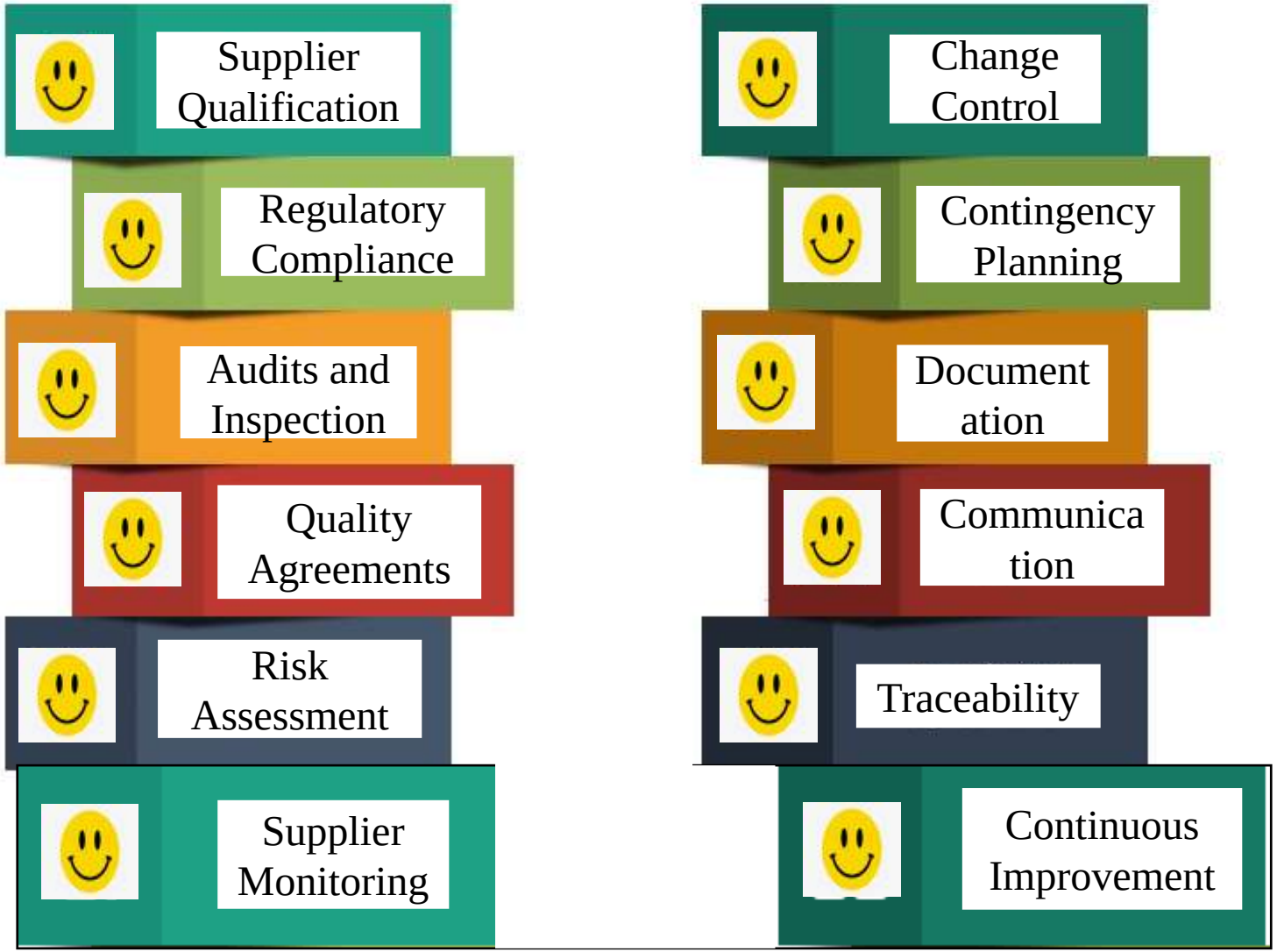
Supplier Verification & Risk Management in the field of Healthcare

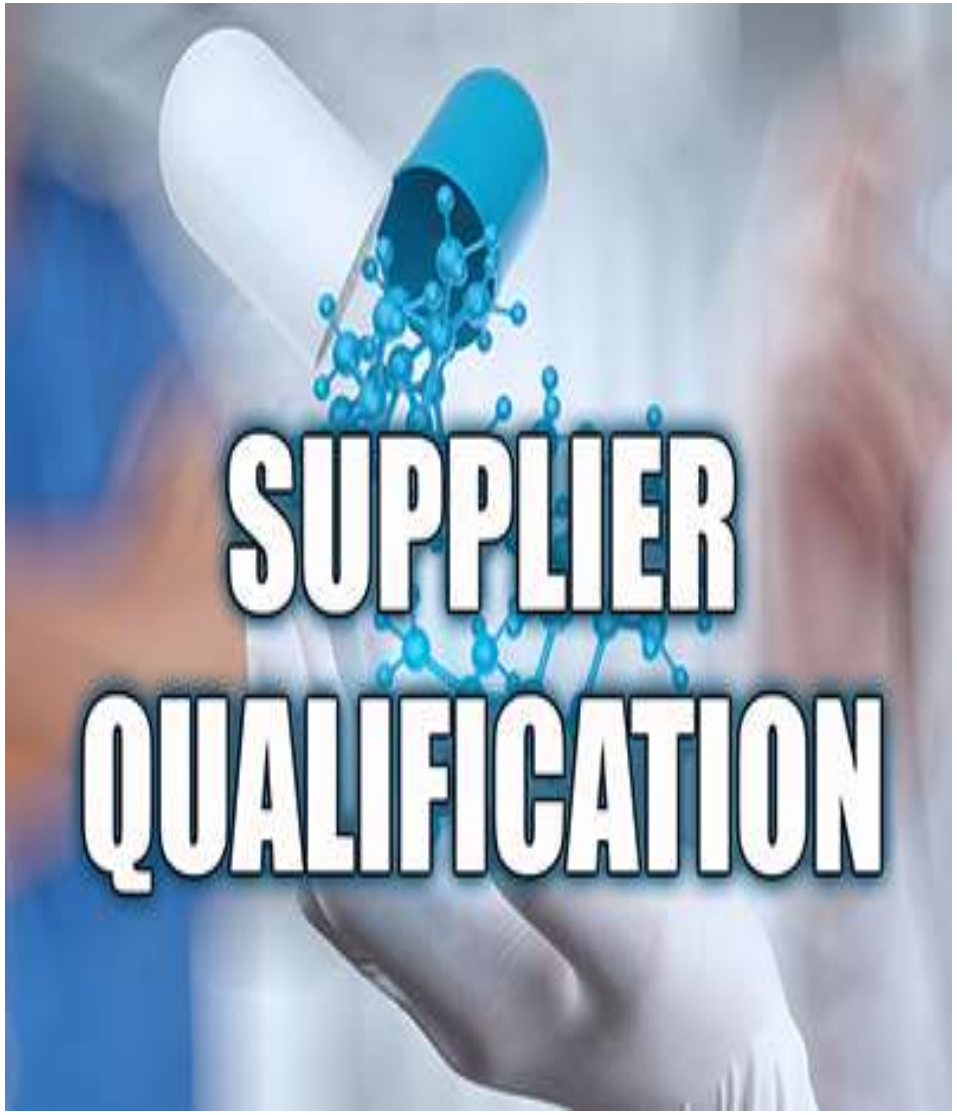
In the field of Healthcare, especially while dealing with the lives of people, we have to be extremely careful in purchasing Pharmaceutical ingredients.

It is important to understand that these are highly specialized healthcare products and cannot be treated as *"mere commodities".*

To ensure that we buy highest quality excipients, it is critical to verify correct Supplier of pharmaceutical excipients and thereby doing the having Risk Mitigation approach.

KEY STEPS FOR ENSURING PROPER SUPPLIER VERIFICATION & RISK MANAGMENT




SUPPLIER
QUALIFICATION

Established Company
Quality Product
Good Track Record
Supplier Qualification Criteria
Strong Documentation
Positive Financial Standing
Quality control Process

Role of EXCiPACT in Supplier verification

- These fatal tragedies have taught us that it is not sufficient to only apply the principles of Good Manufacturing Practice (GMP) to the manufacture of the excipients but also that Good Distribution Practice principles (GDP) must be applied by all organisations involved in excipients distribution.

- Excipients quality can be better assured if all steps in the supply chain, from manufacturer through to user, adopt suitable standards that are capable of independent verification.

What is EXCIPACT?

A voluntary self regulated initiative of the global pharmaceutical excipie manufacturing, distributing and processing industry supported by excipie users.

EXCIPACT ensures current GMP and GDP requirements are applied pharmaceutical excipients through a recognized auditing and certificatic process thereby increasing safety and reliability as well as transparency of tl pharmaceutical supply chain .

EXCIPACT is accepted from all major stakeholders including relevant authoriti globally.

As an independent organization EXCIPACT will be able to objectively set CGM and CGDP standards today and in the future.

EXCIPACT™ certification provides a cost efficient method of ensuring cGMP ar CGDP are applied throughout the pharmaceutical supply chain by reducing tl audit burden.

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EXCiPACT Vision and Benefits

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Simple: Easy to understand and apply for all stakeholders

IPEC is partner with EXCiPACT globally for certification

Regulatory Compliance

- Regulatory Compliance ensures that the suppliers meet all relevant regulatory requirements, such as GMP practices and other industrial quality standards.

Regulatory compliance is the cornerstone of a resilient and trustworthy supply chain, ensuring that the quality and safety of excipients remain unwavering, and the path to innovation remains open.

Audit And Inspection

- Auditing is a verification activity, such as inspection or examination, of a process or quality system, to ensure compliance to requirements.
- Onsite audit and inspection of Supplier facility give a 360 degree review of their manufacturing process, GMP and GDP practises and Quality standards.

Why ? When? How?

Why to Audit :

1. Assess Vendor Capabilities
2. Maintain Product Quality
3. Ensure Regulatory Compliancee
4. Analysis market trend

When to Audit:

1. Initial Vendor Selection
2. Regular Monitoring
3. Significant Changes

How to Audit:

1. On-Site Inspection
2. Records Review
3. Sampling and Testing

Quality Agreement

* Clarity of expectation

*Consistency

*Documentation & Records

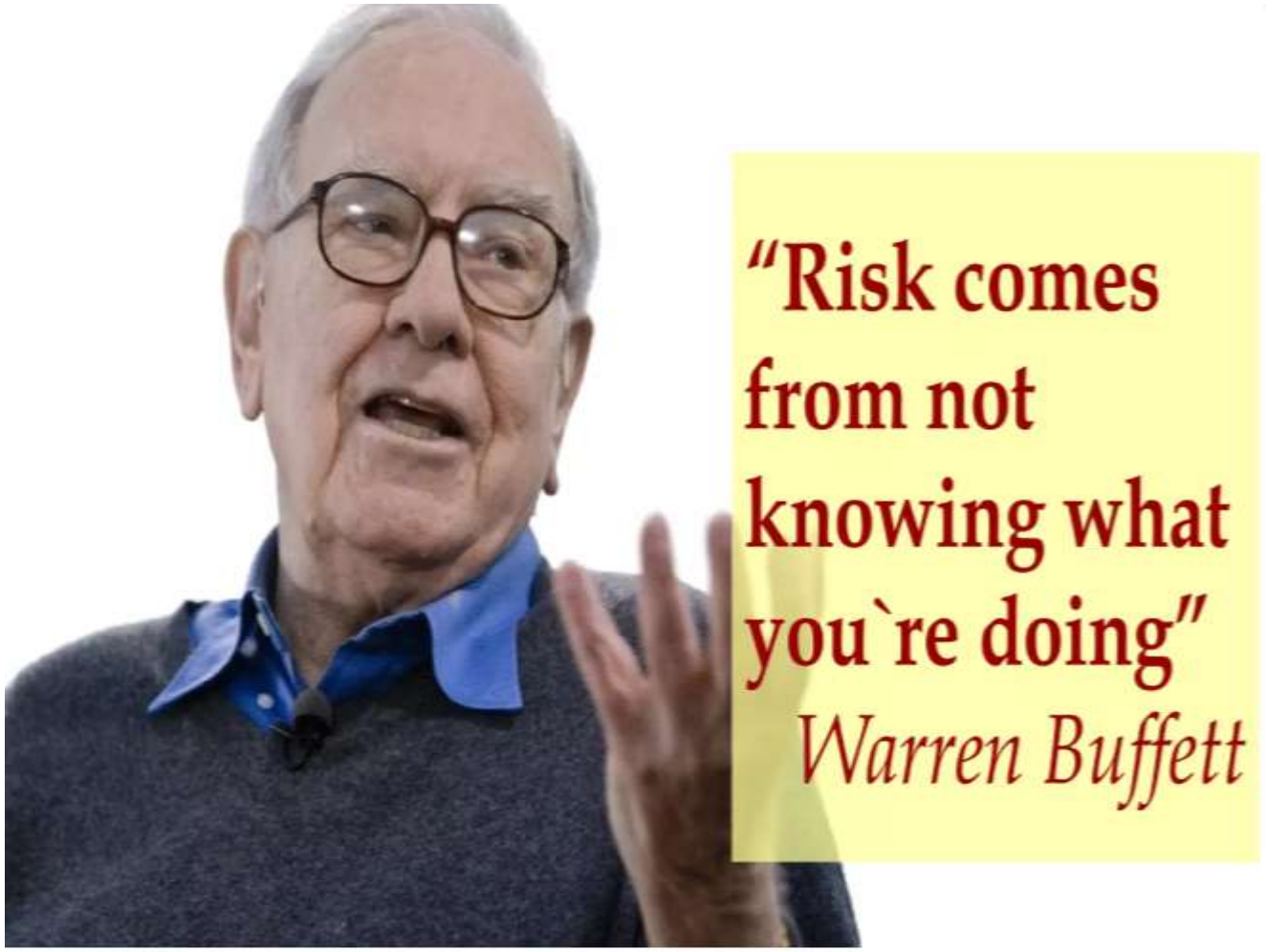
*Reliability

*Conflict Resolution

* Legal Protection

As businesses grow, they require a reliable supply of quality raw materials. An effective way to ensure supplier compliance is by using quality agreements.

RISK ASSESMENT



Evaluate the Criticality of each Excipient and asses potential risk associated with its use.

Supplier Monitoring

Its important to implement a system for ongoing supplier performance monitoring.

HOW?

1. Define Objectives and Criteria
2. Identify Key Suppliers
3. Set Frequency and Schedule
4. Data collection and Analysis
5. Action plans and corrective actions
6. Continuous improvement
7. Review and Adjust

Change Control

- Change control to manage and document changes to a system in a controlled and compliant manner.
- It develop procedure for managing any changes made by excipient supplier, such as process modification or sourcing of materials from new suppliers.
- Change control in the manufacturing industry is a structured process that involves documenting, evaluating, and implementing changes to processes, equipment, or materials to ensure they meet quality and regulatory standards

Contingency planning

Have a plan for supplier disruption or quality issues to ***minimize the impact on your manufacturing process.***

HOW.. HOW.. HOW…

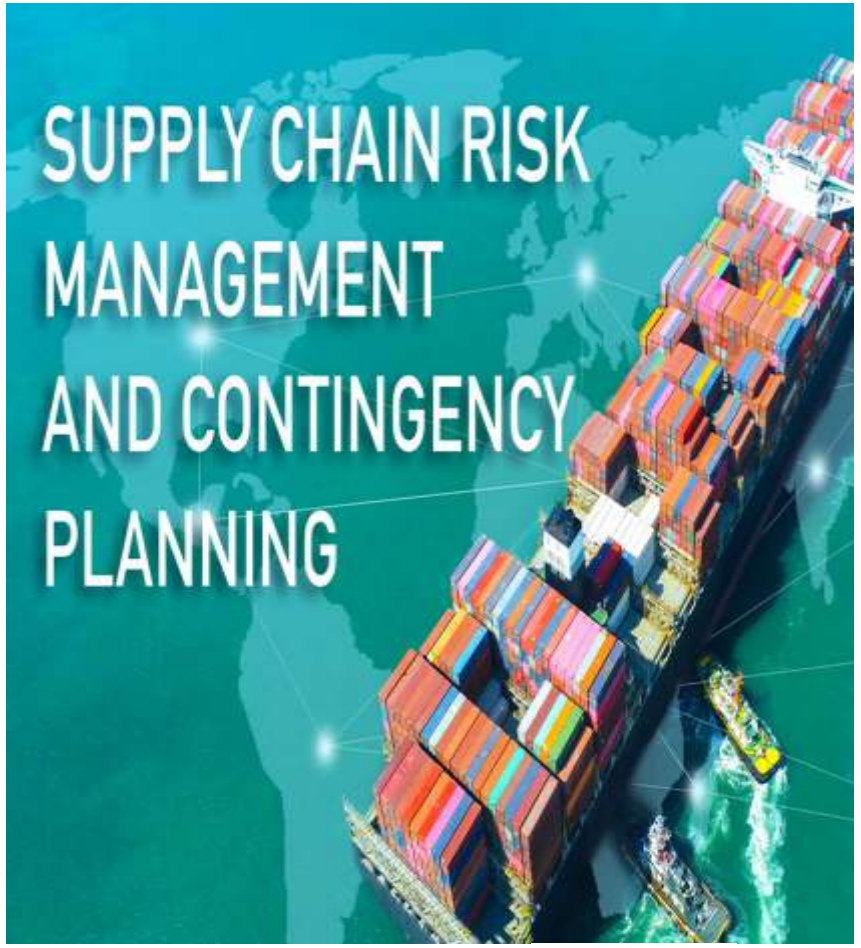
Supplier with the excipients expertise.

In urgency should deliver quickly.

Manufacturing and storage capacity of size.

Strong team support.

In case of disruption like covid etc., Local supplier can be of great help.



DOCUMENTATION

SUPPLY CHAIN AND LOGISTICS
CHANGE CONTRL RECORDS
QMS DOCUMENTS
MATERIAL AND SUPPLIER DOCUMENTS
REGULATORY COMPLAINCE DOCUMENTS
QUALITY CONTROL AND TESTING RECORDS

Communication

Communication ensures the efficient flow of information between the excipients supplier and the pharmaceutical manufacturer.

Transparent communication impacts supply verification and Risk Mitigation positively

Effective communication helps in verifying the authenticity, quality, and compliance related to pharmaceutical excipients at various stages of the supply chain.

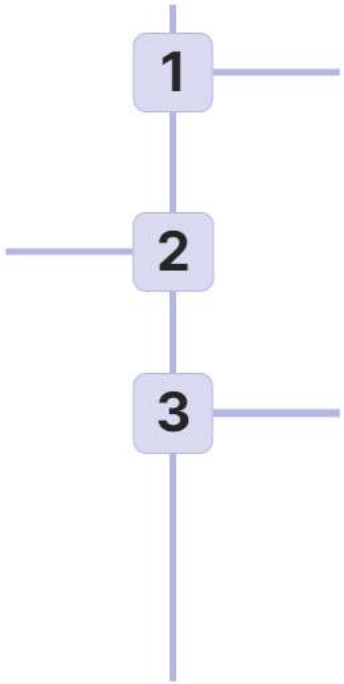
Communication – Impact on You

ASPECTS	IDEAL SUPPLEIR
QA Capabilities	Dedicated and well versed quality team
R&D/Application lab	Recognized R&D department with sufficient resources
Customer Care	Well-structured customer care team
Transparency	Transparent and automated systems for better clarity
Backend Support	Robust and efficient back end support to enable seamless communication, data protection and the agility to innovate and stay competitive in today's technology-driven world.

Traceability

To track and verify the origin and journey of the excipient and materials through the supply chain.

Knowing where products come from and where they've been is essential for safety and accountability.

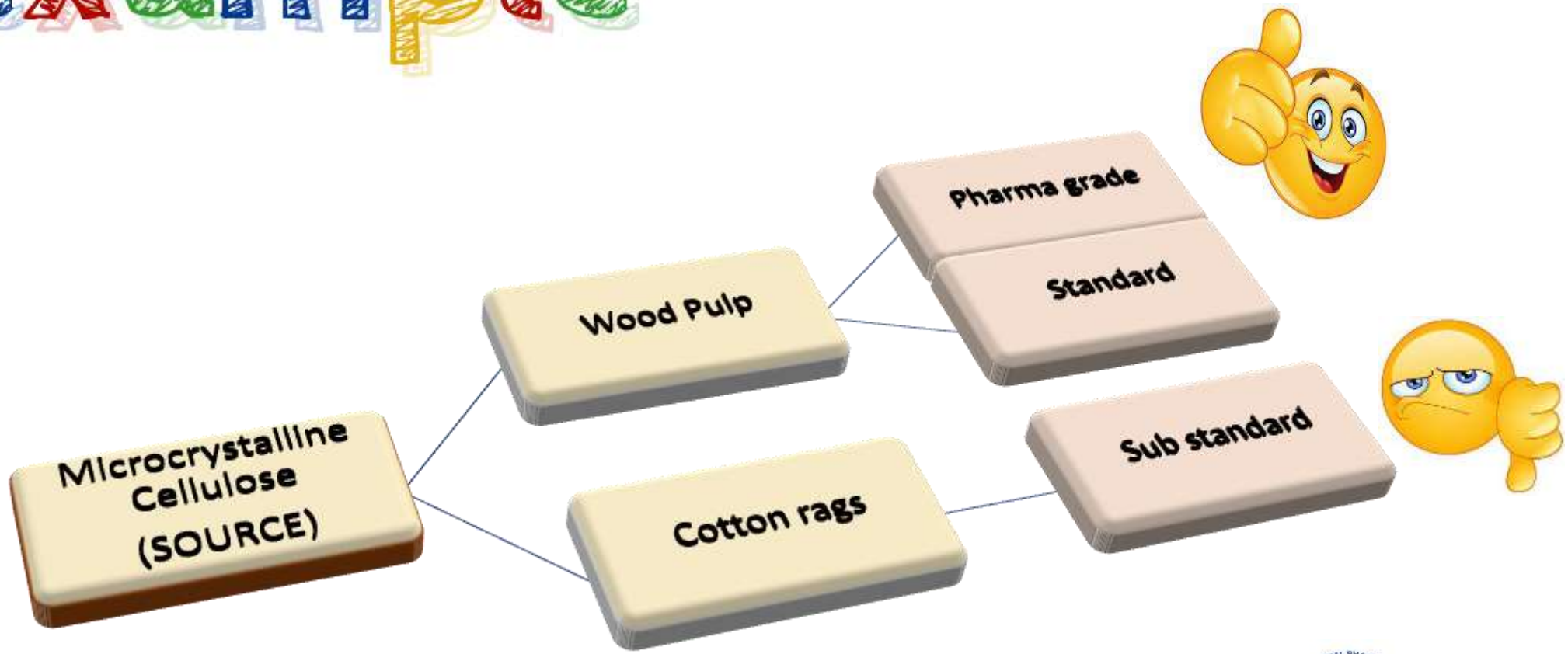


Quality Control : By implementing traceability in supplier verification, you can identify and address quality control issues before they become major problems

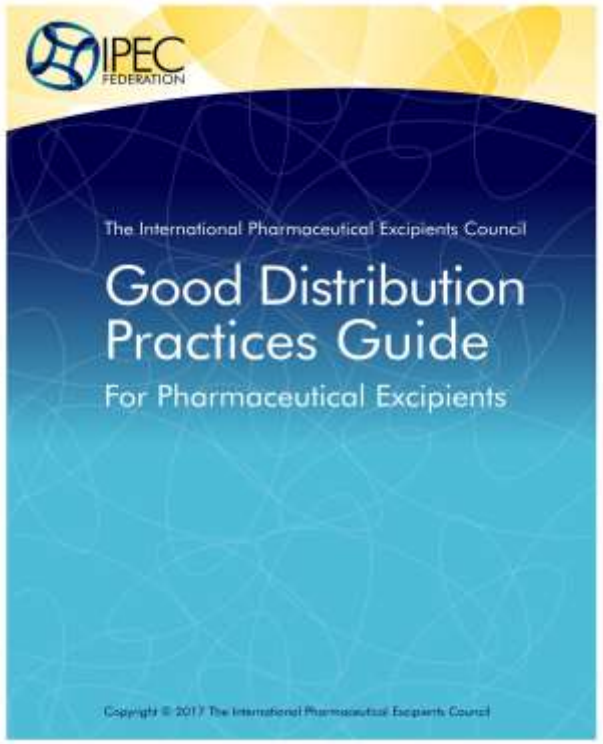
Risk Management : Increased visibility and accountability mean you can manage risks more effectively.

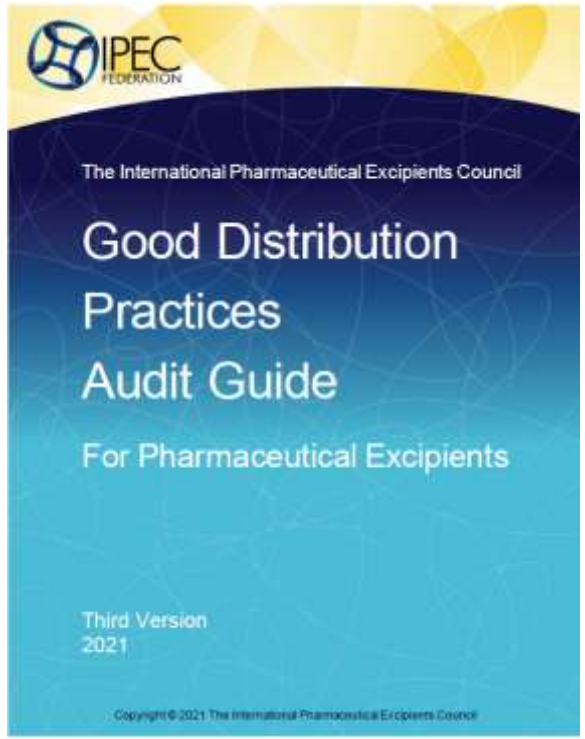
Transparency: We can demonstrate transparency to customers and stakeholders by tracing products throughout the supply chain.

example


Microcrystalline Cellulose (SOURCE)
Wood Pulp
Cotton rags
Pharma grade
Standard
Sub standard

IPEC Federation Good Distribution Practices (GDP) Guide for Pharmaceutical Excipients and IPEC Federation GDP Audit Guide





(https://www.ipec-europe.org/guidelines.html)

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Updated 2023 IPEC Federation Position Paper on Supply Chain Security

- *August 2023*

Free to download from IPEC Europe & IPEC Federation Websites

(https://www.ipec-europe.org/pps.html)
(https://ipec-federation.org/position-papers/)

Updated 2023 IPEC Federation Position Paper on Supply Chain Security

IPEC Federation Position and proposed actions

- **The IPEC Federation believes that the tools to ensure security of the excipient supply chain are already available**

- Areas that require greater awareness and compliance by all actors involved with the supply chain of pharmaceutical excipients:

- Awareness and robust application of guides, standards and regulatory requirements
- Starting materials to be purchased from qualified and approved suppliers
- Purchase of ingredients suitable for use in pharmaceutical products/pharmaceutical grade excipients, no use of industrial grade chemicals as pharmaceutical excipients
- Robust incoming goods inspection, quality control testing and product release according to applicable monographs or equivalent validated and appropriate internal method(s)
- Full traceability of the supply chain back to the original excipient manufacturer
- Awareness and application of Risk Management principles
- Training system and records

Continuous Improvement

Continuous improvement in supplier verification is an ongoing effort that requires dedication, collaboration, and a commitment to enhancing the efficiency and effectiveness of your supply chain operations. Regularly assess your processes, seek opportunities for improvement, and adapt to changing business environments and industry standards.

Conclusion

If we want to stop the deadly incidences like Gambia….

If we don’t want to risk the human lives due to low quality pharma excipients…

We need to ensure thorough supplier verification and Risk Management. By ensuring the reliability, quality, and compliance of excipient suppliers, pharmaceutical industries can mitigate risks, maintain product safety, and uphold regulatory standards. This proactive approach not only safeguards patient health and lives but also strengthens the overall integrity of the pharmaceutical supply chain, fostering trust and confidence among stakeholders.