

RINDA FAIRANI

Pharmacist I QA Manager I Quality Ambassador I GMP/ISO Governance I Pharma

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Based In Indonesia

Executive Profile

Quality and compliance leader with more than 20 years of experience in pharmaceutical manufacturing (local and multi national company). Proven capability to lead quality operations, transforms enterprises QMS and elevate compliance to global standards.

Expert in GxP, ISO governance, quality culture transformation, regulatory engagement and strategic risk management. Driving alignment with global quality frameworks while enabling market growth, and regulatory reputation.

A strong people developer and cross functional influencer who partners effectively with Supply Chain, R&D, Manufacturing, Engineering, HR/People, Regulatory affairs, global quality/technical operation networks and Commercial Team to deliver Right First Rime Manufacturing, Inspection readiness and sustainable compliance.



CORE LEADERSHIP CAPABILITIES

Strategic and Quality Leadership

- Enterprises QMS Transformation
- Site Governance
- Global Quality Standard Integration

Compliance, Risk and Regulatory

- GMP, GDP, GDocP, GLP, HAS 23000
- ISO 9001 I 14001
- Audit dan CAPA Governance
- Regulatory Authority Engagement (BPOM, MoH)

Quality Operational Excellence

- Improving Customer Satisfaction
- Manufacturing Quality and Validation
- Change control and Deviation oversight
- Supplier and External Manufacturing Quality

Leadership and People Development

- Organizational capability building
- Quality Culture Transformation
- Cross Functional Alignment
- Executive Stakeholder Engagement

Professional Experience

QA Manager, Exeltis Indonesia 2013 – 2025

1. Quality in Operation : Led and improved product quality performance with focus on recalls, deviations, OOS, complaints and backlogs
2. Quality Compliance and Inspection Delivery : Led and implemented a robust global quality management system to ensure that our products met current requirements
3. Innovation and Quality Excellence : Modernized the Quality function in line with current industry trends and regulatory expectations
4. Team Capability and Culture : Connected our organization, developed our talent and leveraged our quality culture

QA Manager, Sampharindo Perdana 2002 – 2013

1. Led the site to successful GMP Certification
2. Led process validation, change control, deviation and quality risk management
3. Qualified new and alternate source for business continuity and improved material reliability
4. Developed and validated analytical methods
5. Completed qualification of HVAC, PW system and critical manufacturing equipments

PROJECT MANAGEMENT AND ACHIEVEMENT

3 Big Projects of Quality Improvement :

- 1. Site Quality Maturity Improvement**
- 2. Supplier Management**
- 3. Crisis Management due to EG/DEG Issues and Mitigation**

I. SITE QUALITY MATURITY IMPROVEMENT

Establish comprehensive strategic system in order to improve Quality maturity level at Semarang site, simple but still in compliance. Comprehensive approach has been established which are Quality system improvement, Quality culture improvement, Readiness inspection's program and Right first time mind set and processes. The goals are readiness inspection every day with maximum 3 majors finding, maintain quality and right first time culture, accelerating the product release by improving right first time documentation and reduce final product release lead time

CHALLENGE

- Find the gap analysis between GMP guideline with our GMP
- Identify the process needed for QMS and implementation at all area
- Assure the availability resources and information necessary to support the operation and monitoring the process
- Improve quality mindset, culture and system
- Reduce cost of non conformance and improve customer satisfaction
- Build GDocP commitment from Top to Bottom at all area
- Production people have not completed the batch record in the real time yet
- Finished product release rate is too high and Right first time manufacturing rate is too low

STRATEGY

- Do gaps assessment to all chapter GMP and place CAPA. Parallel do separate action plan
- Clear out and classify perform 5R/5S as the foundation. Training and implementation 5P as basic GMP
- Continuous training GDocP for production people, and having QA Inspector on shop floor to review batch record in real time and increase awareness of Production people
- Process validation report and deviation report not included in the FPR calculation
- Inspection preparation : System readiness, stability readiness, document readiness, people readiness
- Managing inspection and organization arrangement during audit

I. SITE QUALITY MATURITY IMPROVEMENT

RESULTS :

- Readiness inspection : No Major observations and only 3 minor observations from FDA BPOM in September 2022 and No Major observation during CMO audit in December 2022.

- All Quality KPI's are in green

Increase Right first time (RFT) from 45 % become 90%

Reduce FPR (finished Product release) from 10 days become 3 days

ADVANTAGE :

- Simple and stay in compliance and Quality is a key as a license for Pharma Operations.

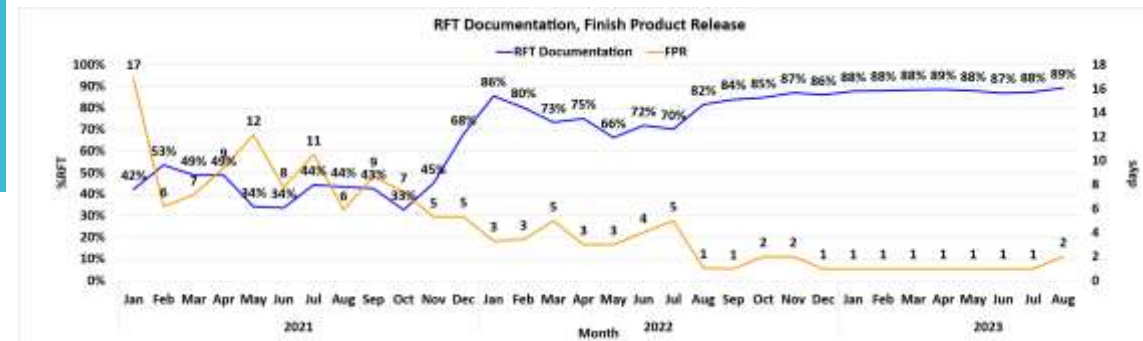
- Proactive approach to identify quality risk at site and establish comprehensive approach to ensure simple / agile operations but still in compliance and increase the quality maturity level at the site, through compliance assessment and systems that include process knowledge, management understanding, compliance with SOPs, deviation investigations and effective CAPA, good quality management, quality Culture, readiness inspection program and reduce product release processes

		METRIC	TARGET	2020	2021	2022	2023	AVERAGE
PRODUCT QUALITY	MANUFACTURING RIGHT FIRSTTIME		≥ 95 %	100	100	100	99	100
	PACKAGING RIGHT FIRST TIME		≥ 95 %	100	100	100	98	100
	LOT ACCEPTANCE RATE (REPROCESS)		≥ 95 %	100	100	100	100	100
	LOT ACCEPTANCE RATE (REJECT)		≥ 95 %	100	100	100	100	100
	OPEN OOS		Record	4	25	10	10	12
	RECALLS		Record	0	0	0	0	0
MANAGEMENT CONTROL	COMPLAINT		Record	0	3	1	1	1
	DEVIATION	ON-TIME	≥ 95 %	100	98	100	100	99
		TOTAL OVERDUE	< 5%	0	4	0	0	1
	CAPA	ON-TIME	≥ 95 %	99	100	100	100	100
		TOTAL OVERDUE	< 5%	0	0	0	0	0
	REGULATORY CAPA	ON-TIME	100%	100	100	100	100	100
		TOTAL OVERDUE	0 %	0	0	0	0	0
	STABILITY PULL COMPLIANCE		≥ 95 %	100	100	100	100	100
	STABILITY TEST COMPLIANCE		≥ 95 %	99	100	100	100	100



All quality metrics are in green with key highlighted No Recall, No Critical Observation

Exeltis Indonesia as the Winner Quality Awards 2023 from HQ Madrid



II. Supplier Management

Establish comprehensive strategic system to assess reliability Suppliers. Comprehensive approached which are ensuring approval and qualification of all GxP Suppliers, present general overview of supplier qualification principles that will assure consistent approach across all sites, reviewing and approval supplier quality documents for adequacy and update in the QMS, perform risk assessment and audit for suppliers, maintain approved supplier list and distribution to concerned departments, and following supplier qualification status.

CHALLENGE

- Authorities demand Audits to API suppliers, even these are not direct suppliers
- Missing Audits required by SOP
- Difficult to control and update the QTAs (Quality Technical Agreements) because its lacking resources
- External companies subcontracted to perform Audits must be included in the master list of suppliers
- Absence of Data Base containing information about suppliers (service, raw material, trader/broker)
- Supplier's subcontracted companies' disinformation
- Absence of a Data Base with Suppliers Certifications/Accreditations/Documentation

STRATEGY

- Must be established in the QTAs and must be informed to Supplier
- Inclusion of this in the SOP Supplier Management/Qualification
- Implementation of Supplier Management/Qualification SOP
- QTA Templates must be published to obtain an easier review
- Meetings with the relevant departments
- Review communication between different departments and levels

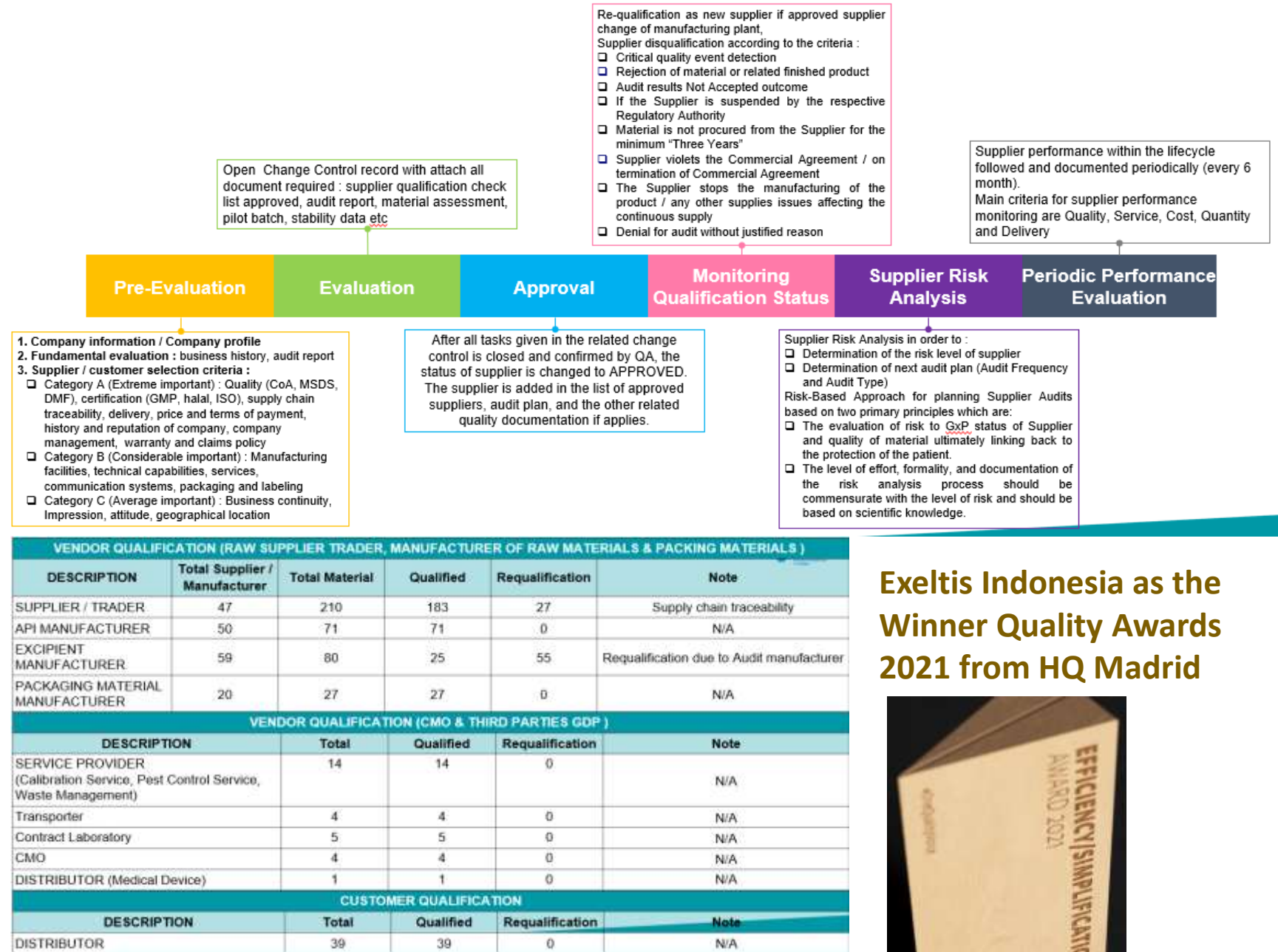
II. Supplier Management

RESULTS :

- Authority inspections : No any observations during the audit
- Increase supplier compliance
- Maintaining security and integrity of supply chain to minimize risk of substandard materials or counterfeit products
- Easy to trace supply chain
- Have an alternative supplier to ensure business continuity

ADVANTAGE :

- Human rights, labor rights, environmental protection and anti corruption
- Qualified vendors can be used for all sites



Exeltis Indonesia as the Winner Quality Awards 2021 from HQ Madrid



III. CRISIS MANAGEMENT DUE TO EG/DEG ISSUES AND MITIGATION

- We have done to deal with the crisis situation and uncertainty , massive, crazy requirement from BPOM, MoH due to Indonesian Government banned all liquid products in Indonesia due to the side effect issue of EG/DEG

- Team demonstrated high performance culture with sense of urgencies, deal with ambiguity related to regulatory requirement and uncertainty condition, required strong team with excellence collaboration and teamwork, creates group synergy, maintain motivation, spirit and mentality, never give-up, persistence's, align with all function related, high level communication with all stake holder especially the Health Authority

Dual work: a team in the front line and a team in the backstage perfectly coordinated by WhatsApp to respond asap to all the requirements of the BPOM during the two full days face to face meeting

- Impact in money and possible impact on HC, that is, on individuals and families

CHALLENGE

- Potential not continue to sell the all liquid products in to the market with annual sales value, sales volume approximately USD XXX
- Potential recalled all the liquid products at the market (Distributor's warehouse)
- Potential destroyed all the liquid products at the factory's warehouse
- Impact in money and possible impact on HC, that is, on individuals and families

STRATEGY

- Analysis and build strategy for acceleration in testing and collect data : Understanding the BPOM requirement, conduct EG/DEG test with a lead time of 3 days, make a risk analysis of EG/DEG testing of materials and finished products against product stocks on the market based on distributor data and product safety analysis based on Daily Intake values
- Day by day monitoring : Follow up to Third Party Lab, follow up readiness of internal data, follow up to BPOM regarding update issue
- **Desk Verification : 30 November 2022 :** Desk Verification for Health Supplement Category. **Thursday, 1 December 2022 :** Desk Verification for Drug Category
- Dual work: a team in the front line and a team in the backstage perfectly coordinated by whatsapp to respond asap to all the requirements of the BPOM during the two days of the meeting

III. CRISIS MANAGEMENT DUE TO EG/DEG ISSUES AND MITIGATION

RESULTS :

- We had done deal with crisis situation, deal with ambiguity and uncertainty and crazy requirement from BPOM by having Desk verification by BPOM with successful results and Exeltis Indonesia become faster to resolve this crisis compare to the competitors which get approval to produce and distribute syrup products.

Company image and reputation are maintained

Avoid potential recalled all the liquid products at the market with the total value about : USD XXX

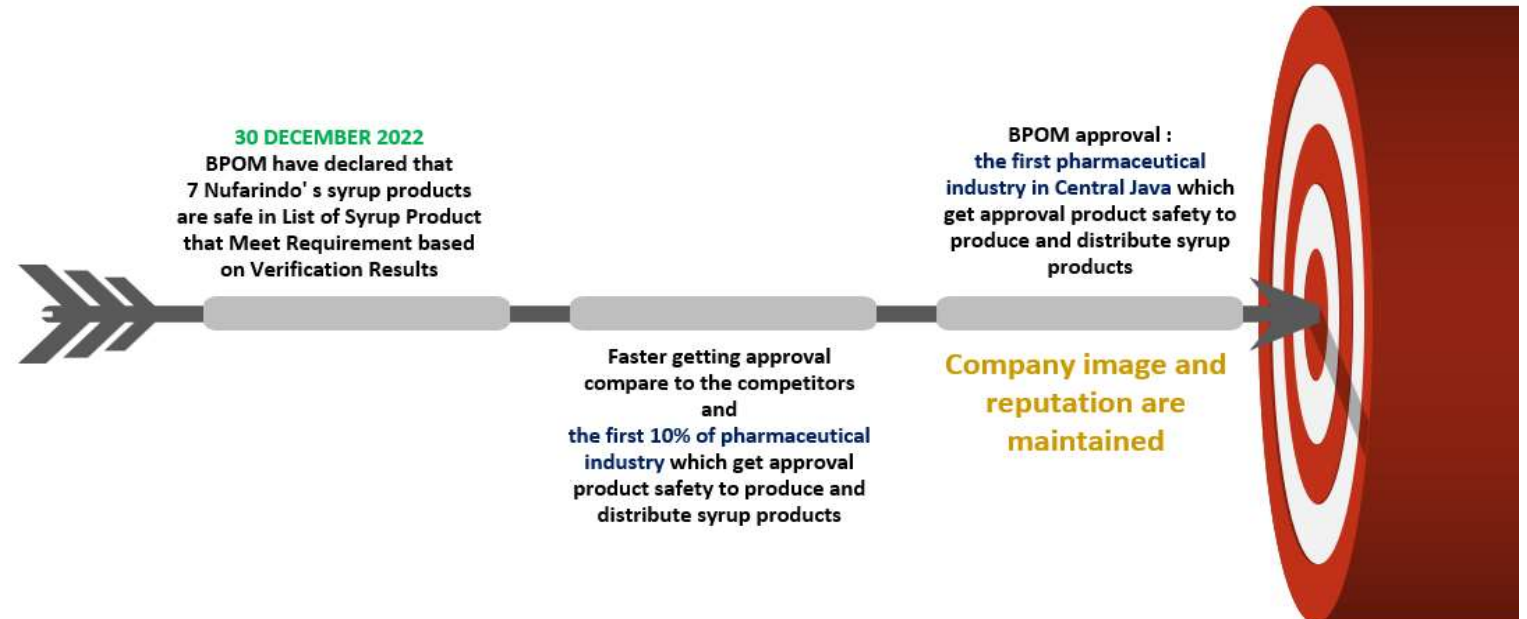
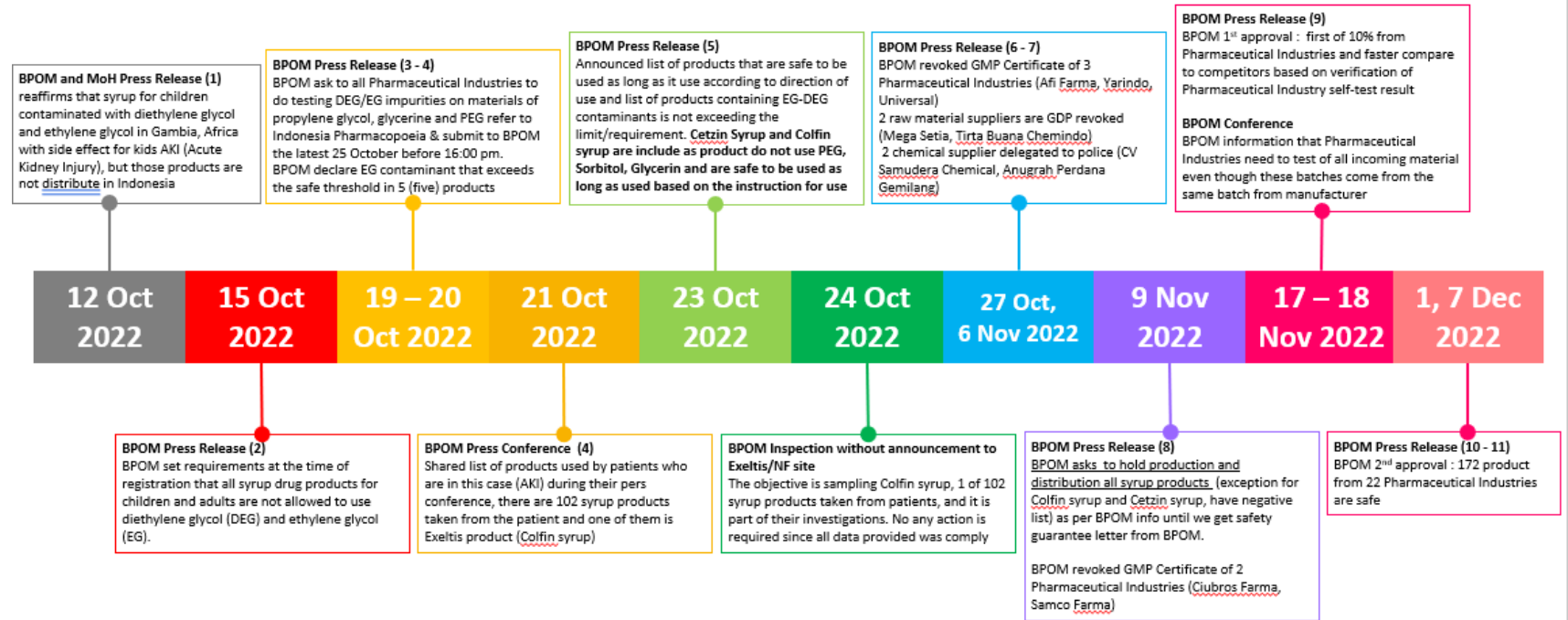
Avoid potential destroyed all the liquid products in the factory warehouse with the total value about : USD XXX

Avoid potential not to continue to sell the all liquid products in to the market with annual sales approximately : USD XXX

ADVANTAGE :

- We had done to deal with ambiguity from Indonesian FDA and internal situation, crisis situation with winning spirit team, synergy, can do attitude, persistence, never give up to resolve this crisis and faster result compare to the competitors which get approval by BPOM to resume and distribute syrup
- High risk impact since BPOM release updated 5 company GMP revoked, 2 raw material suppliers are GDP revoked, 107 products MAH revoked, 2 chemical supplier delegated to police

HISTORY OF ISSUE ETHYLENE GLYCOL/DIETHYLENE GLYCOL ON SYRUP PRODUCT



Other Projects as Quality Improvement

Project Name	Deliverable	Project Lead
GMP Recertification	Obtain GMP certificate that valid for 5 years (4 dosage forms)	Rinda Fairani
Tolerable daily intake total EG/DEG	Assure that total EG/DEG in oral liquid formula meet the requirement refer to MoH issued FI VI suplemen II	Rinda Fairani
Food Supplement remediation	Compliance testing refer to perka BPOM No. 17 year 2019	Rinda Fairani
Facility Improvement	Improve GMP compliance level, additional buffer bottle , bottle blowing, personnel airlock and pass box for RM to minimize risk of contamination, Improve personnel flow and materials flow	Lead by Production Manager. Rinda Fairani as team member
Trackwise Digital System Project	QMS in the cloud with integrated module that allow correct compliance with the basic activities of quality system management, facilitating the monitoring of execution, the detection of trends and efficient decision making	Lead by Global Quality Director. Rinda Fairani as team member

Other Projects as Quality Improvement

Project Name	Deliverable	Project Lead
Regulatory Compliance	Ensure adherence between dossier approved by BPOM and actual implementation	Rinda Fairani
Reduce Calibration Frequency	Simplification and reduce complexity, improve process and compliance, improve efficiency in QA	Rinda Fairani
Migration FI VI	Full compliance testing or using risk analysis excipients refer to BPOM template	Rinda Fairani
Serialization Project	Following BPOM guidance No. 33 year 2018, Improve GMP compliance level	Lead by Production Manager. Rinda Fairani as team member
Alternate Source Project	Having second source, supply continuity and compliance	Lead by Procurement Manager. Rinda Fairani as team member
Quality Culture	Improve quality mindset through 5R/5S Winner Quality Awards 2019 from HQ Madrid	Rinda Fairani

-RINDA FAIRANI-

