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GOOD REGULATORY PRACTICE

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What are Good Regulatory Practices?

Internationally recognized processes, systems, tools and methods for improving the quality of regulations (Health Canada)

Regulatory Affairs quality standard that is based on trained people who understand their professional role and work in an environment that follows standards and processes (Good Pharma, Vol 22, issue 4,2013)

There is no officially published or legally binding GRP standard thus RA professional to define what GRP means in their particular environment

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Role of RA Professional in GRP

- Provide strategic and technical guidance throughout the life cycle of a product
- Monitor trends and changes in the regulatory environment and assess impact to product
- Partner with regulatory agency for timely registration and launch

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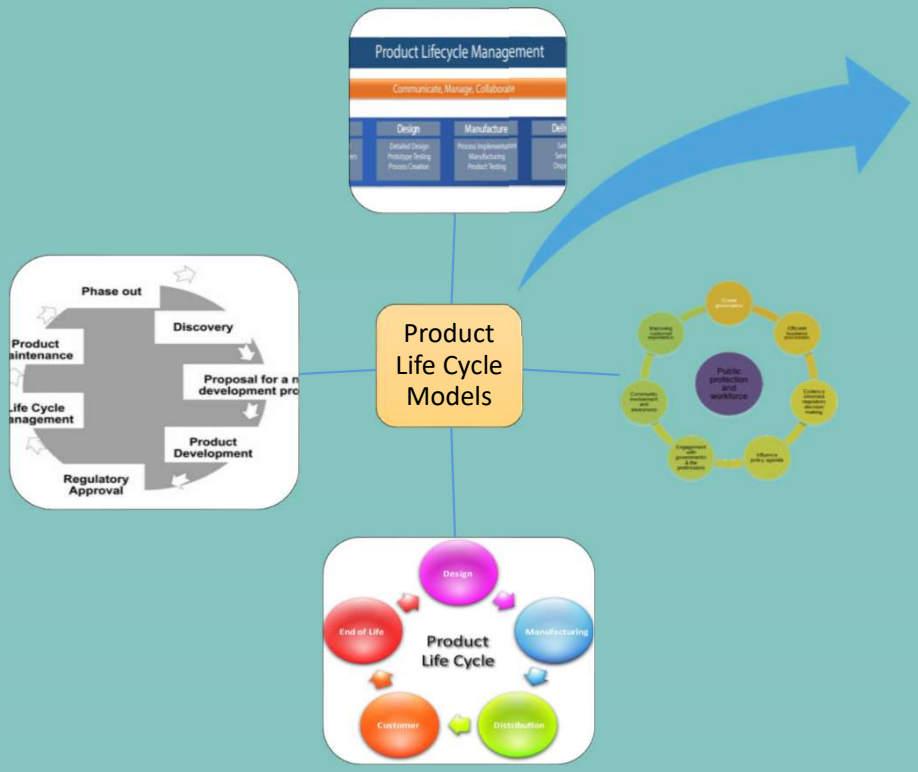
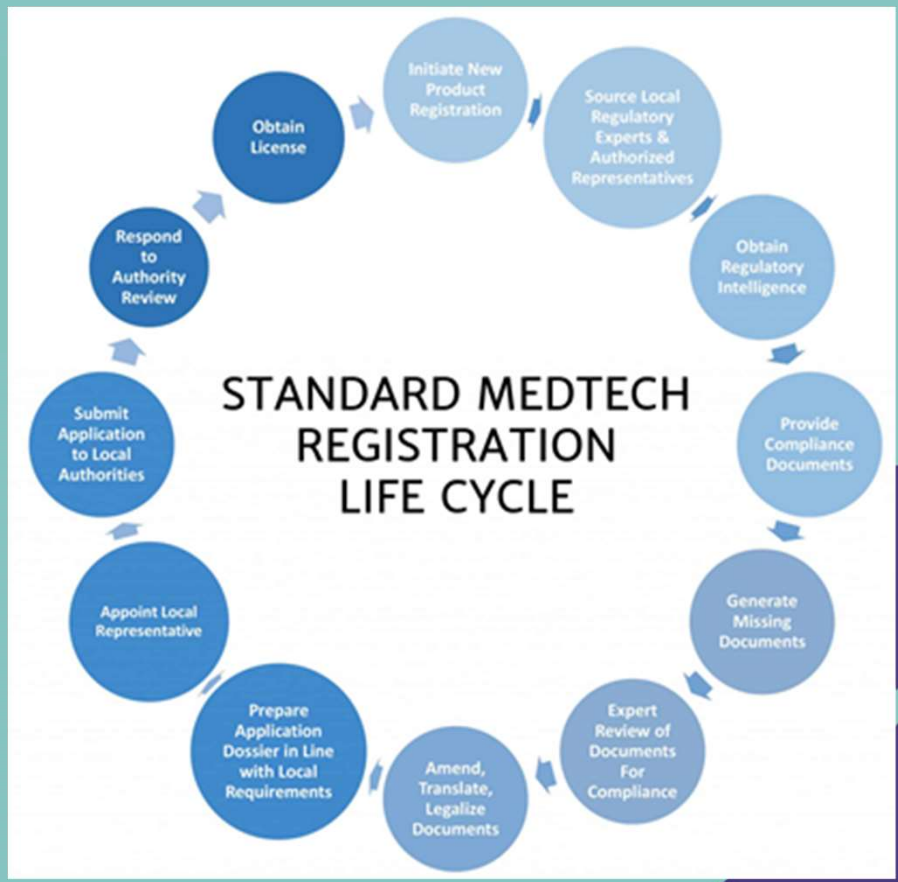
Product Life Cycle and GRP





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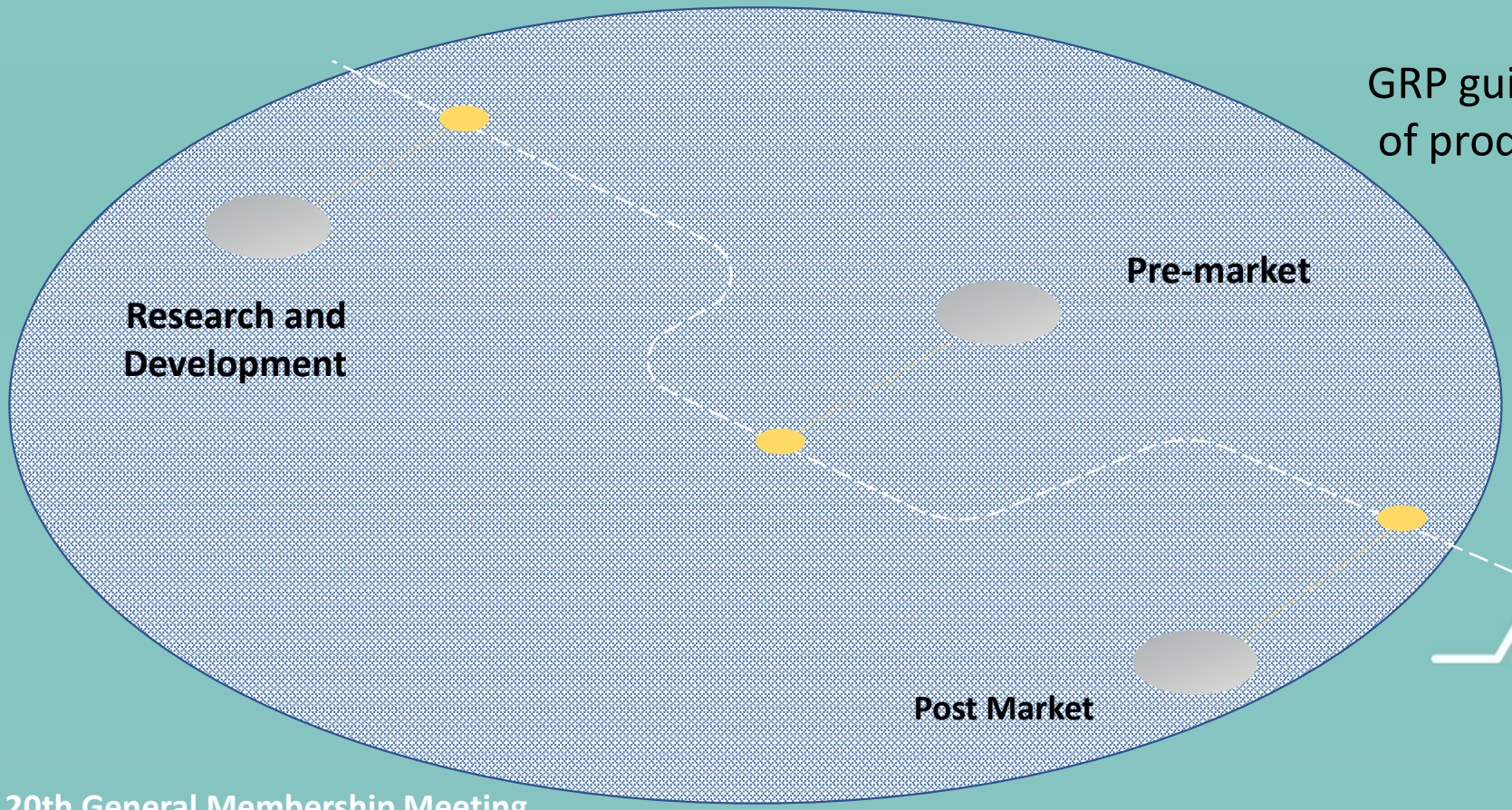
Product Life Cycle and GRP

GRP guides all phases of product life cycle



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Research and Development Phase

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Regulations and Standards

Research & Development Phase

Product Testing

Research & Development Phase

Dossier Development

Research & Development Phase

Support Files Maintenance

Research & Development Phase

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Regulations and Standard

Regulatory Intelligence

It can take 10-12 years for a health product to progress through the entire development process, from laboratory to hospital. Throughout this process, and even after a new product (drug or device) reaches the market, there are huge amounts of legislation in place to ensure the treatment is as safe and efficacious or effective as possible. Regulatory affairs, as its name suggests, encompasses all of the regulatory protocols surrounding its development, and ensures these are adhered to at each stage of development.

Legislations, standards, policies –are well defined and easily accessible

- Our role? Comprehensive knowledge of standards to be able provide strategic and technical guidance in target markets

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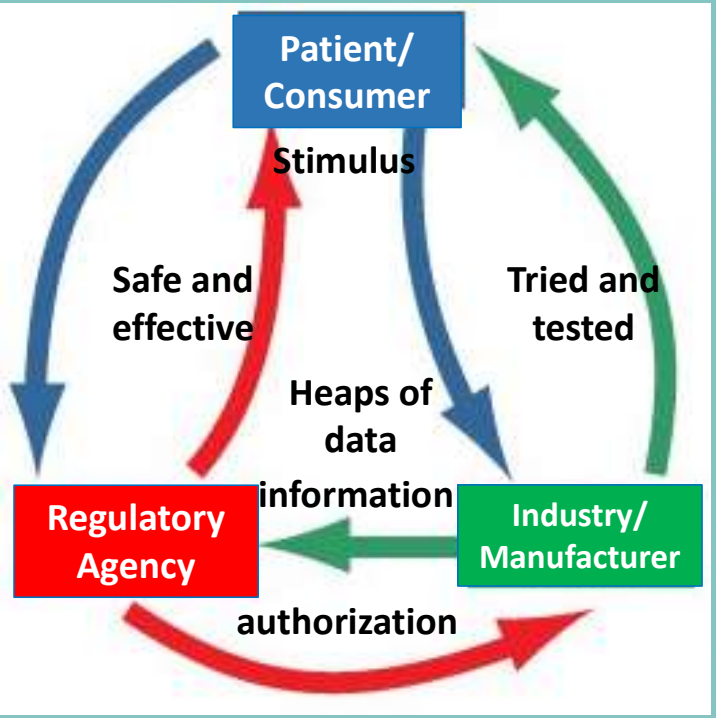
Regulatory Intelligence



Product Testing

Market Trial
Clinical Evaluation
Biocompatibility
Risk Management
Risk Classification

- A 3-way check and balance for a safe and effective portfolio
- Set a standard –based method to contribute to cost-effective development
- Mindful of Change controls for an accurate profile

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Dossier Development

Regulatory Intelligence

Microsoft Excel Worksheet

"Even the most scientifically complete study and the best
results do not guarantee the granting of a marketing authorization of a product if the regulatory authority is unwilling to accept the way the data are presented."

The RA professional compiles all the relevant technical documents during product development (source) and at the time of submission (distributor level) and ensures **an appropriate presentation** of registration documents to the regulatory agencies.

- Identify target markets ahead in plan to allow dossier flexibility
- Consider regulatory trends and decide between basic compliance vs potential requirements
- Avoid deviation from prescribed format.

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Support Files Maintenance

Regulatory Intelligence

Proper documentation in area of GMP, GLP, GCP
to support robust dossier
Contributes to the designing of the development programme-validation, stability studies and performance tests

- Review of documentation to ensure it to be clear, consistent and complete and conclusions are explicit.

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Pre-market Phase

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Dossier Compilation and Review

Pre-Market Phase

Submission Strategy

Pre-Market Phase

Regulatory Communications Negotiation

Pre-Market Phase

Tracking and KPI

Pre-Market Phase

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Submission Strategy

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Elements of an effective regulatory strategy/plan include the following:

- Identifies applicable regulations
- Defines submission type and requirements, what to do if unable to meet requirements
- Contains specific project deliverables including timing, responsibilities, and resources
- Defines testing requirements (if any)
- Identifies potential risks and mitigation plans
- Defines any special requirements such as facility inspection/registration, PMS
- Describes any pre and post submission interaction with regulatory agency officials (e.g. consultations)

Strategy=Broad Reg Elements
Plan=Specific Steps

- Strategy shares the story of how to meet goal
- Identifies fastest approval route
- Prevents rework-saves $$$ and time
- Developed with CFT- a living document

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Dossier Preparation & Review

Dossier: Collection of documents managed as a single, consistent, structured and unified that relates to a product applied for registration.

Dossier Preparation Considerations

Planning **Understanding of requirements** **Use of Checklists**

Inputs from CFT **Format** **Review/Recheck**

Completeness **Consistency**

Creation of "strong dossier" is dependent on knowledge of requirements.

- Insert explanations/documents to bridge data gaps in dossier
- Check list supports documented tracking of dossier content
- As MAH, you should know everything about your product
- Put yourself in the shoe of reviewer –rely on experience!

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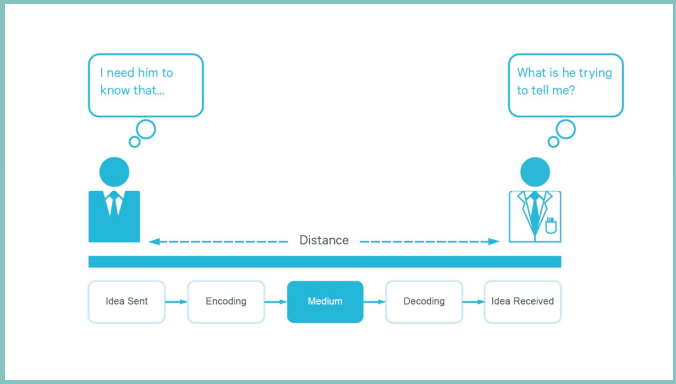
Communication and Negotiation

Regulatory Intelligence

"RA professional should seek an optimal partnership with the regulatory agencies to guarantee a smooth running of all registration procedures – allowing for a timely launch" - Susanne Goebel-Lauth



Communication/s to FDA include but not limited to

- Formal correspondence and query Response (letter, email, etc)
- Informal verbal communications (phone, face to face)
- Meetings (registration consultations, public mtgs,etc)
- **Dossier**

*Key is clear and precise messaging

- An effective communication is directly proportional to an effective negotiation
- Review, revise, review…and learn from experience!
- Maintain professional approach in communications/negotiations
- Maintain respect at all times!!!

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KPIs and Tracking

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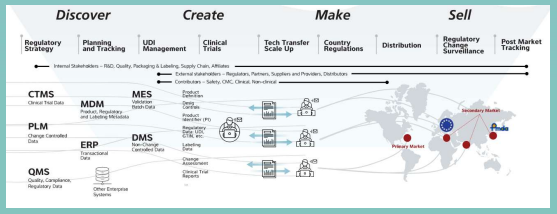
A Key Performance Indicator is a measurable value that demonstrates how effectively a company/individual is achieving key business objectives.

Why is goal setting important?

- Sets performance expectations
- Allows alignment with stakeholder direction

Why is regulatory tracking important?

- Documented measurement of performance
- Can be a basis for upgrading performance
- Provides user with ready reference re product history
- Supports on time submission (renewals, commitments, admin)



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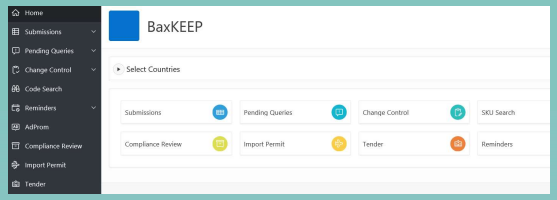

- Provide monthly KPI report to management
- Trackers are impt for work planning and measurement
- For non-systems tracking-always back up (server,cloud)
- If using excel , use single worksheet for easy filtering of data
- Match your tracker with Calendar

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Post Market Phase

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Post Approval Changes

Pre-Market Phase

Complaints Handling / FCA

Pre-Market Phase

End of Life / End of Service Life

Pre-Market Phase

Good Distribution Practice

Pre-Market Phase

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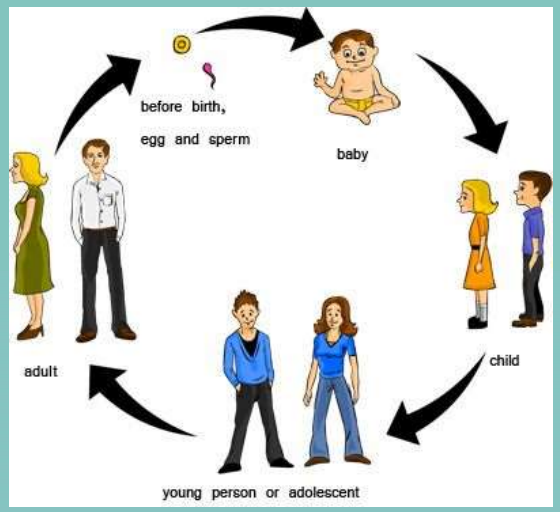
Post Approval Changes

Regulatory Intelligence



Source of Changes:

- Change in local circumstances → Change of importer/ distributor; change of importer/ distributor address
- Local business decision/ local regulatory strategy → discontinuation of products; consolidation of product registrations; addition of product codes
- Design changes from manufacturer (continuous improvement) or as corrective action to product issues, e.g., additional warning on labels; improved safety features
- Compliance with international regulations; e.g., European MDR/ IVDR
- Change in manufacturer/ supplier circumstances → change in address/ new manufacturing site/ raw material supply issues

Post Approval Changes are inevitable!

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Post Approval Changes

Regulatory Intelligence

What does Phil. FDA require from CPR holders?

QWP-CDRRHR/LRD-02 Annex 05
Rev. No. 06 Date Effective: 10 February 2020

10. We shall change the brand name so submitted should the proper authority decides with finality that we have no right to appropriate and utilize said brand name;
11. We acknowledge and agree to indemnify and/or hold FDA (CDRRHR/BFAD) free and harmless against any and all third party claims arising from the acceptance of such brand name of the product for registration with BFAD.
12. Product covered by this declaration will not undergo any change in the ownership, registrant's address/location, manufacturer, ingredients, formulation, size, reference number, use, manufacturing process (if applicable), labeling or commercial presentation, and packaging of the product covered by the CPR without prior approval of this office.
13. We acknowledge and agree that in the event that there is an unauthorized change in the ownership, its address/location, manufacturer, ingredients, formulation, size, reference number, use, manufacturing process (if applicable), labeling or commercial presentation, and packaging of the product:
    i. CDRRHR may automatically suspend the LTO and/or CPR of the product
    ii. We will voluntarily recall the product from the market; and
    iii. We will indemnify and/or hold CDRRHR free and harmless against any and all third party claims and/or actions pertaining to the above unauthorized change(s).

Post Approval Changes require FDA approval prior to implementation.

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Post Approval Changes

Change of Business Name & Address of Manufacturer/ Trader/ Importer/ Distributor
Change in ownership
Change in shelf life

18. VARIATION OF CERTIFICATE OF PRODUCT REGISTRATION FOR MEDICAL DEVICES AND IN-VITRO DIAGNOSTIC DEVICES

Center/Office/Division	CDRRHR-LRD
Classification	Highly Technical
Type of Transaction	G2B - Government-to-Businesses
Who May Avail	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	Php500.00 + Php10.00 Other fees: Extension of shelf life: Php1,000.00 + Php10.00 Change in brand name: Php2,500.00 + Php25.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Change of Business Name and Address of Manufacturer/Trader/Importer/ Distributor	
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking Number	Applicant
2.Valid License to Operate (LTO) reflecting the new business name and address of manufacturer/trader/importer/distributor with the source reflected in the LTO	Applicant
3. Original Certificate of Product Registration (CPR) - Should submit back and front sides	Applicant
4. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant

CHANGE IN OWNERSHIP (Inclusion/Deletion or Change in Trader/Importer/Distributor)	
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Valid LTO reflecting the source	Applicant
3. Termination of Contract/Deed of Assignment	Applicant or Principal/Source/ Manufacturer
4. Agreement with the new company - must be valid	Applicant or Principal/Source/ Manufacturer
5. Original CPR - Should submit back and front sides	Applicant
6. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant

REQUEST FOR CHANGE OF SHELF LIFE	Where to secure
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Previously submitted stability data	Principal/Source/Manufacturer
3. Real time data supporting the change of shelf life - Must be signed by the person who performed the analysis	Principal/Source/Manufacturer
4. Copy of CPR - Should submit back and front sides	Applicant
5. Complete labeling requirements - Submit current and proposed labels	Applicant or Principal/Source/Manu

The FDA listed the requirements for each type of change in the FDA Citizen's Charter.

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Post Approval Changes

Change of Manufacturing Site (Same subsidiary)

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Change of Manufacturing Site (Same Subsidiary) With No Change in The Formulation, Equipment, and Manufacturing Procedure	Where to Secure
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. . Submit justification or supporting documents to show that the proposed manufacturer is a subsidiary of the current or approved manufacturer	
3. Letter from the manufacturer stating that there is no change in the formulation, equipment and manufacturing procedure	Principal/Source/Manufacturer
4. Valid LTO	Applicant
5. Copy of submitted Notification of Source - The list of sources should reflect the proposed manufacturing site	Applicant
6. Formulation (for solutions) or List of Raw Materials (with the corresponding amount of raw materials used, if applicable) issued by the current and proposed manufacturer	Principal/Source/Manufacturer
7. Manufacturing flowchart (current and proposed) Include brief narrative description of the manufacturing flowchart	Principal/Source/Manufacturer
8. Finished product specification (current and proposed)	Principal/Source/Manufacturer
9. For Imported Products – authenticated or apostiled GMP/ISO Certificate reflecting the new manufacturing site The GMP/ISO certificate should be valid	Principal/Source/Manufacturer
10. Sterilization process and latest result of sterilization validation conducted/issued by the new manufacturing site	Principal/Source/Manufacturer
11. Valid ISO Certificate of the sterilizing company (if there is a change in sterilization company)	Principal/Source/Manufacturer
12. Copy of CPR - Should include back and front sides	Applicant
13. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant or Principal/Source/Manufacturer

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Post Approval Changes

Change of Brand Name/
Change of Storage Condition
Additional indication
Change of Packer/ Repacker

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Change of Brand Name (From Generic to Brand, Change of Brand to Another, Deletion of Brand)	Where to Secure
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Should include back and front sides	Applicant
3. Certificate from IPO for local brand name. For imported products, the manufacturer's declaration that allows the use of the brand name.	Applicant
4. Official letter from the product owner regarding the change of brand name and declaration that there is no other change to the product/label except for the brand name	Principal/Source/Manufacturer
5. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant or Principal/Source/Manufacturer

Change of Storage Condition	Where to Secure
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. .Approval letter issued by a government agency or notified body	Principal/Source/Manufacturer
4. .Studies to support the additional indication	Principal/Source/Manufacturer
5. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Principal/Source/Manufacturer

Change of re-Packer/Packer	Where to Secure
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Termination of contract with the previous re-packer/packer	Applicant or Principal/Source/Manufacturer
3. Agreement of with the new re-packer/packer	Applicant or Principal/Source/Manufacturer
4. Copy of CPR - Submit front and back sides	Applicant
5. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Principal/Source/Manufacturer

Different changes require different documents.
Regulatory intelligence is key to planning and execution of the change

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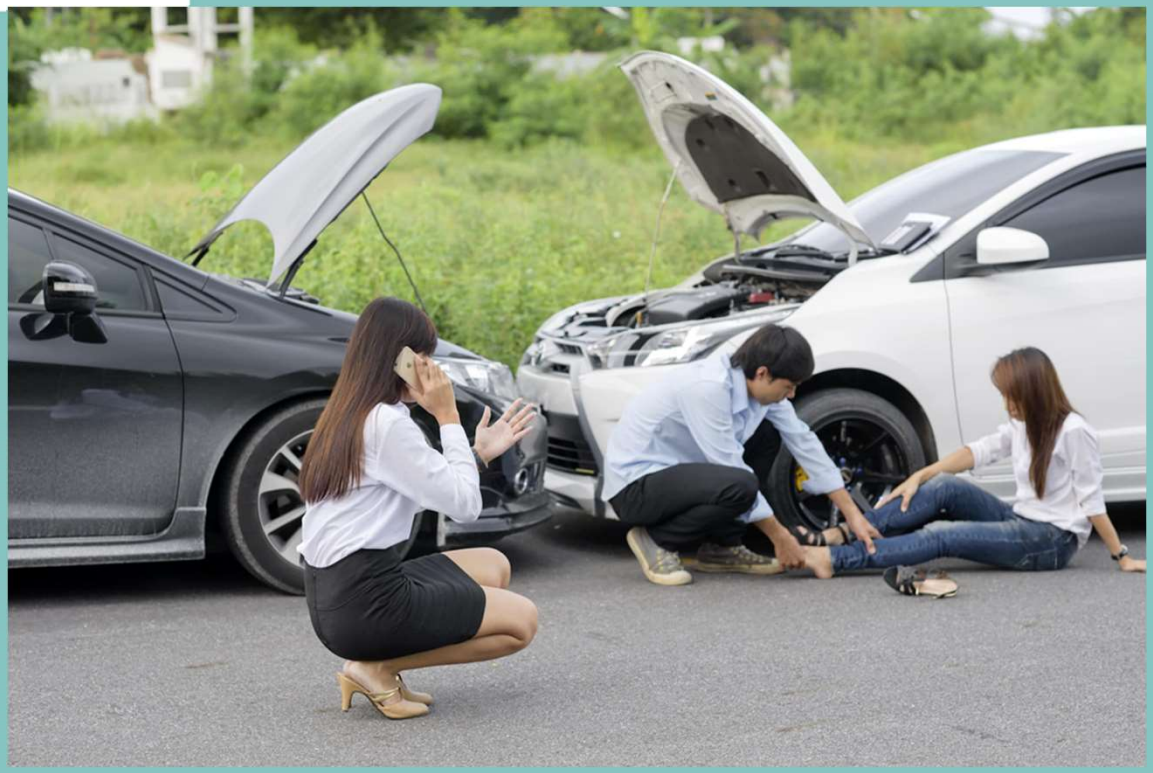
But what about unplanned events?



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Risk management plan

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A set of health product vigilance activities and interventions designed to identify, characterize, prevent or minimize risks to health products, and the assessment of effectiveness of those interventions.

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Field Safety Corrective Actions (FSCA)

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"Field Safety Corrective Action (FSCA)" means any action taken by a product owner to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device. This may include:

1. the return of a medical device to the product owner or its representative; (RECALL)
2. device modification which may include: (a) retrofit in accordance with the product owner's modification or design change; (b) permanent or temporary changes to the labelling or instructions for use; (c) software upgrades including those carried out by remote access; (d) modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device.
3. device exchange;
4. device destruction;
5. advice given by product owner regarding the use of the device.

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Recall

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Recalls are actions taken to remove a product from the market. Recalls maybe initiated by FDA or are voluntary actions on the part of manufacturers and distributors to carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise deceptive.

FDA Regulations on Recall:

- Bureau Circular No. 8 s. 2001
- FDA Circular 2016-012

All recalls are FSCAs, but not all FSCAs are Recalls.
Recalls are subject to FDA regulations.

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Field Safety Corrective Actions (FSCA)

Regulatory Intelligence

Policies and procedures should be in place to provide for actions to be taken:

a) in the event of a recall of products held in stock

b) in recalling products on behalf of the principal

c) to generate records of recalled products.

d) Support the principal in tracing product distribution for other reasons not related to product safety/recall actions (i.e. products exported to markets where the product is not authorised)

e) in notifying customers of product recalls notifications

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Field Safety Corrective Actions (FSCA)

Regulatory Intelligence

- If a recall is initiated by the principal or the authorities, assist in identifying the location of the recalled products
- Document all recalls; Records of all recalled products received into the warehouse should be kept
- Stock that has been recalled and is not immediately destroyed should be placed in quarantine until disposal so that it cannot be sold in error or leak and contaminate other goods.
- Ensure all recalled products are accounted for until disposal occurs.
- Send out the customer communication sent by principal within the designated timeline

The conduct of FSCAs have a significant impact on patient safety! It should take high priority.

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Complaints

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CUSTOMER COMPLAINT: any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market.

An unvalidated complaint is still a complaint and must be recorded.

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Complaints

Regulatory Intelligence

Policies and procedures should be in place to provide: a) receipting and recording of complaint details; b) adequate methods of handling and communicating complaint content; c) adequate methods of measuring and evaluating complaint content; d) resolution of complaints and prevention of a recurrence.

- Complaints should be investigated to identify the reason for the complaint (e.g. packaging process, transportation, storage).
- Complaints relating to the distributors/wholesaler's own activity, including transport, should be evaluated.
  - Records of these complaints and the actions taken should be maintained.

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Installation, Maintenance, Service

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Distributors/wholesalers must refer to technical documentation made available to them by the principal regarding installation and maintenance/service instructions include directions for ensuring proper installation so that the instrument will perform as intended after installation. The distributor/wholesaler must make these documents available to the person(s) actually installing the instrument.

The person installing the instrument must ensure that the installation, inspection, and any required testing

are performed in accordance with the available instructions and procedures and must document the inspection and any test results to demonstrate proper installation.

- Installation and maintenance activities must be carried out by trained personnel only.
- Installation and maintenance as well as the associated test/validation phases must be properly documented and archived.

Only TRAINED personnel should perform installation, maintenance & service as per manufacturer's procedures.

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Good Distribution Practice

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Good Distribution Practice
Building premises

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Policies and procedures should be in place to provide:

a) Good housekeeping and protection for all products stored within the building

b) Safe and secure access to the building

c) Safe and secure access to the products stored

d) Security of the premises and the products stored within.

Good Distribution Practice begins with having the proper building premises.

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Good Distribution Practice
Building premises

Regulatory Intelligence

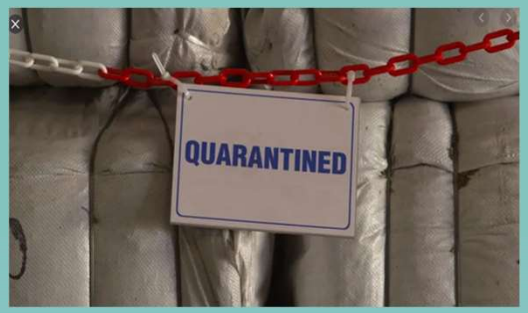
Sufficient space for separate receiving and dispatch areas

Protects the products from weather conditions

Free of rodents, vermin, birds, pets and pests

Pest control program with available records

Physically separated areas for isolation of faulty, returned and expired goods as well as recalled RD products accessible only to authorized employees.



Clean and well-maintained; Prompt cleaning of spillage

Sanitation program with available records

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Good Distribution Practice
Temperature Controlled Storage Facilities

Regulatory Intelligence

Policies and procedures should be in place to provide storage conditions that ensure the maintenance of quality and safety of stored products.

Monitor temperatures using suitable temperature recording devices Equipment used are regularly calibrated/ serviced/ maintained with available records

There must also be a power back up system available which ensures that an accidental power break down does not give any risk to the stored products.

Store products in accordance with the storage conditions specified on their label
Temp excursions will affect product quality! Seek advise from the manufacturer if this occurs.

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Good Distribution Practice
Stock handling, Equipment & Stock Control

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Policies and procedures should be in place to provide for stock handling, stock handling equipment and stock control.

- Storage areas should enable segregation and identification of the various products
- Ensure the implementation of a physical separation from other suppliers' products.
- Prevent mix-up, contamination or deterioration of the goods, damage to packaging or confusion of products
- Store product off the floor (e.g. on pallets or shelves) to reduce exposure to dust and moisture, and to help facilitate cleaning.
- Ensure that products due to expire first are sold and distributed first (First Expiry First Out (FEFO))

Proper stock handling ensures product quality and allows for better traceability.

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Good Distribution Practice
Supply and delivery

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Policies and procedures should be in place to ensure that only products approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. Procedures should also be in place to ensure adequate methods of transportation to achieve safe, secure and timely delivery of all products from their point of collection to their destination. Transportation conditions should maintain the quality of the products being transported.

- Dispatch
  - Records for the dispatch of products should be prepare: a) Date of dispatch b) Name and address of the customer c) Quantity of the products i.e. number of boxes and quantity per box d) Batch number and expiry date e) Transport and storage conditions of the products (temperature range) f) A number to allow the identification of the delivery order

There should be enough information available to enable the traceability of products. Such records should facilitate the recall of a batch of a product .

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Good Distribution Practice
Supply and Delivery

Regulatory Intelligence

- Transportation
  - Use clean delivery containers that to prevent damage or deterioration for the products delivered
  - Maintain temperature requirement of products during transport
  - A system should be in place to:
    - give assurance of the trustworthiness of personnel
    - keep vehicles secured when unattended
    - enable the return of signed receipts obtained from the authorized recipients of the goods in paper or electronic form.
    - ensure safe, secure and timely delivery of products and for dealing with incidents

Products should be stored at the required temperature during transportation

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Good Distribution Practice
IT Systems

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Where a computerised stock management system is in place it must be demonstrated, through appropriate validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly.

- This system should be capable of:
  - providing the following information: a) product code b) Batch number c) Expiry date d) Storage Location e) Material status (blocked/non blocked)
  - Blocking non saleable items
  - Providing a report for expired goods and goods with short expiry date
  - Access only by authorized person
- Back up data must be retained for the period as defined for that record type.
- Procedures to be followed if the system fails or breaks down must be defined.

Computerised systems must be validated!
Garbage in – garbage out

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Good Distribution Practice

Return of Unused and/or Damaged Goods from Customers

Policies and procedures should be in place to ensure all unused and/or damaged products returned from customers other than through the Return of Unwanted products are accounted for until disposal occurs.

- Returned to saleable stock if examined and assessed by a person authorised to do so:
  - they are in their original unopened containers, with intact labels and packaging and bear a valid expiry date; and
  - there is no reason to believe that they have been subject to adverse environmental conditions (temperature monitoring records must be available);
  - there is no reason to believe the goods have been tampered with or are contaminated;
  - on receipt, they are packed separately from other goods and accompanied by a separate Returns Note;
  - certain temperature controlled products may never be returned to saleable stock, advice is sought from to identify these
- Products not returned to saleable stock should be quarantined pending disposal, or returned (in accordance with the agreement)

Regulatory Intelligence

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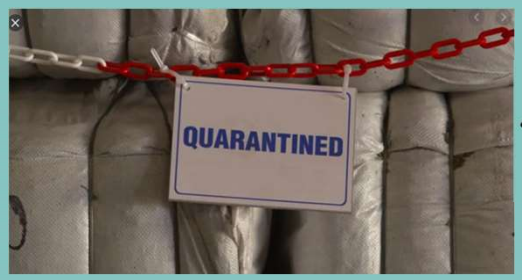
Good Distribution Practice
Damaged Stock and Stock Unsuitable for Sale

Regulatory Intelligence

Policies and procedures should be in place to ensure that damaged products and products otherwise unsuitable for sale are quarantined and accounted for.

- Quarantine stocks which has been damaged or is otherwise deemed unsuitable for sale, temporarily or permanently, so that it cannot be sold in error, misappropriated or stolen or leak and contaminate other goods.
- Quarantine may be achieved through physical isolation from saleable stock or electronically through a warehouse management system or stock control system..



Don't mix good stocks with bad stocks!

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Good Distribution Practice
Example of storage risks

GSP
Cold-chain
Irregular checking
Lack of SOPs
Malfunctioning monitoring equipment
Power-outage(for example, highest risk)
Malfunctioning refrigerator

All Risks relating to the importation, distribution , storage promotion and sales of products must be identified and managed.

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In Summary…….

- GRP is a collection of best practices
- A strong knowledge of regulatory environment is key to successful GRP. Regulatory Intelligence (RI) is KING in RA Profession!!
- Always focus on compliance in all activities- adopt a compliance mindset.
- Complete, Correct and Compliant dossier ensures MoH approval.
- Always put yourself in regulators' position.
- Be professional at all times!