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PHASE 2 DOCUMENT

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Emcure NPD

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Emcure NPD Phase 2

Milestone 1 - Epic 1

1. PIDF

   a) Reference product detail & API sourcing block which we have hidden as per Rahul Patil request but now as mentioned by SID, we would need those again.

   b) InHouse field which we have hidden as per Rahul request we would need those again and will be utilized for PBF costing (In House or Out Sourced)

   c) Every business unit will be able to see PIDF request in list and than they can edit the records. There will be further new business logic for different business units.

      i. Form will have radio button (Every business unit user have to fill this up)

         1. Interested

         2. Not Interested

      ii. If its interested than every business unit need to select the Region and Countries for which it is going to be interested

      iii. After filling region and country

         1. They can update the PIDF form and it will be for their specific business unit only

         2. Here they can not change "Dosage Form, Dosage Type, Molecule Name & In House" apart from that, user can change anything and that will be saved respective to their business unit.

   d) PIDF request can not be approved for 15 days or until all business unit provide their response "Interested / Not Interested".

   e) Once PIDF Request is approved after that no business unit can select Interested / Not Interested.

   f) Once PIDF request is approved it will be process further for those business unit only who marked this as Interested.

g) Need to add 2 more new field into PIDF

  i. Trade Name Required (Boolean) yes / no

  ii. Trade Name Date Registered (It will display only when Trade Name says Yes)

2. IPD Form Changes

  a) We will have all the business units which is active in the system

  i. Form will be enabled for only those business units says interested, for other business unit form will not be there we will have note : "{BusinessUnit} have said not interested on {DateTime} by {User}". OR {BusinessUnit} have not taken any action on this.

  b) Patent Details for Formulation & API

  i. This data should be Country specific so we need to add new column country where every patent details will be as per country.

  ii. All the countries for business unit should auto come which user have selected while saying interested.

  iii. We will have below more fields in this child form

    1. Country

    2. Patent Strategy (Dropdown) These will fetch from db table, but master is not required in this scope.

      a) Other option will be there in dropdown, if that is selected than we need to give textbox to enter value

    3. Patent Type (textbox)

    4. Basic Patent Expiry (Date field)

    5. Other Lmiting Patent Date 1 (Date field)

    6. Other Lmiting Patent Date 2 (Date field)

    7. Earliest Launch Date (Date field)

    8. Any Patents to be Filed (Boolean field)

    9. Earliest Market Entry (Date field)

    10. Estimated Number of generics in the market (textbox)

    11. Law firm being used (textbox)

3. PBF Module Changes

    a)   We will have all the business units which is active in the system

        i.   Form will be enabled for only those business units says interested, for other business unit form will not be there we will have note : "{BusinessUnit} have said not interested on {DateTime} by {User}" OR {BusinessUnit} have not taken any action on this.

    b)   We need another tab "RA" which will have below fields and data will be specific to countries.

        i.   Country

        ii.   Pivotal batch manufactured

        iii.   Last data from R&D

        iv.   BE Final Report

        v.   Type of Submission

        vi.   Dossier Ready Date

        vii.   Earliest Submission - D Excl

        viii.   Earliest Launch - D Excl

           1.   As per selection of some parameters / fields this value will auto come, it have different selection and period

        ix.   Last date to regulatory (Date)

    c)   Enhance the UI for PBF form in terms of usability, we can use tabs and next button click to save the data

    d)   General Tab New Fields

        i.   R&D Responsible person (Textbox)

        ii.   Type of development (Date)

        iii.   Pivotal batches manufactured completed (Date)

        iv.   Stability Results

           1.   Day 0 (Date)

           2.   3 months (Date)

           3.   6 months (Date)

        v.   Some more fields would be required as mentioned below, those are not mandatory fields

General Section / Optional Not Mandatory	Non-standard product	Yes / No
General Section / Optional Not Mandatory	Pivotals	
General Section / Optional Not Mandatory	Batch size	
General Section / Optional Not Mandatory	No. Batches per strength	
General Section / Optional Not Mandatory	Site transfer (if yes, when)	Date
General Section / Optional Not Mandatory	API ordered	Date
General Section / Optional Not Mandatory	API Received	Date
General Section / Optional Not Mandatory	Final Formulation Approved	Date

vi.

vii. Below form would be required to fill data, user will enter into textbox and save the data

	Pack sizes on stability	Pack size 1	Pack size 2	Pack size 3	Pack size n
RnD General Section Readonly data	Strength 1	Types	Types	Types	Types
RnD General Section Readonly data	Strength 2	Types	Types	Types	Types
RnD General Section Readonly data	Strength 3	Types	Types	Types	Types
RnD General Section Readonly data	Strength n	Types	Types	Types	Types

viii.

e) Clinical Tab New Fields

   i. BE Study Results (Date from Bio tab)

f) While filling PBF data we will display only those strength which is applicable for selected business unit.

4. Commercial Module Changes

   a) We need to remove feature of Interested / Not Interested which we have developed as per Rahul Patil request.

   b) We will have all the business units which is active in the system

      i. Form will be enabled for only those business units says interested, for other business unit form will not be there we will have note : "{BusinessUnit} have said not interested on {DateTime} by {User}" OR {BusinessUnit} have not taken any action on this.

5. API Management

    a)   API IPD

        i.   Data for Patent details will be displayed as per region and country

    b)   API RnD

        i.   Data for Patent details will be displayed as per region and country

6. Project Management (POST PIDF)

    a)   What ever the workflow has been selected into PBF form (In House) OR Commercial Form (Out Source) according to that set of tasks should get auto created and will be displayed into Gantt and Task list.

    b)   As of this milestone we will have 2 workflow, one is for Tillomed and another is for Global, we need to have support for this to create tasks.

7. Outsourced /In-licensing products

    a)   If we have this option selected while creating PIDF than we will have different impact

        i.   PBF -> Request will not be visible in PBF form since we are not making product in house.

        ii.   Commercial

            1.   We need additional Tab where option to fill Cost & timeline (Its more or less PBF data, which will be later utilized into PBF Charter)

                a)   It will have 2 dropdown at initial level

                    i.   Project Management Workflow

                        1.   It will be selected here, according to that it will create tasks in project management

                    ii.   PBF Charter Workflow

                        1.   By selection of that auto title & timeline will be populated.

                            a)   User can remove any row or add new row for that data.

8. Master Management

    a)   Workflow for Project Management (As of now we need table only, screen can be developed later in next milestone)

    b)   Workflow for PBF Cost (Outsource) (As of now we need table only, screen can be developed later in next milestone)

c) Masters to manage for RnD (As of now we need table only, screen can be developed later in next milestone)

    i. Type of submission

    ii. National Approval

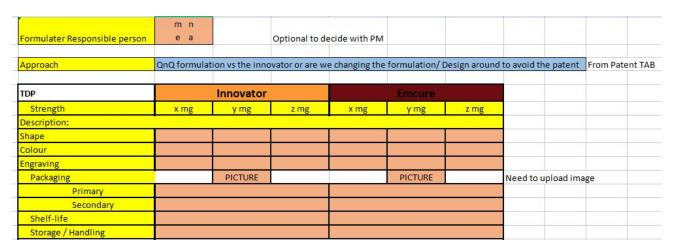   iii. Workflow for different dates

<u>Milestone 1 - EPIC 2</u>

9. PIDF

a) Once PIDF is submitted, we need to send reminder everyday to all the different business unit users who have access to PIDF module. It will be for let them mark, interested / Not interested.

b) PIDF details can be edited until Finance approved the same, since user can extend the countries while filling commercial details, so we should have option to edit the record in PIDF until Finance get approved. Note: Approval of PIDF will not be required in case of extension of countries -- That feature will be implemented on commercial screen

10. IPD Form Changes

a) IPD details can be edited until Finance approved the same, since user can extend the countries while filling commercial details, so we should have option to edit the record in IPD until Finance get approved. Note: Approval of IPD will not be required in case of extension of countries -- That feature will be implemented on commercial screen

11. PBF Module Changes

a) In PBF we should have option to Reject the request, if user rejected from here, this complete project will get rejected (Requested by Mr. Uday Potdar & SID) (This option will be there for if any molecule which can not be developed due to technical issues than request can be rejected)

b) TDP (Trade Dress Proposal) - New section required under the general tab, this form will be completely editable and user will be able to enter all the details and we need to save those.

Formulater Responsible person	m	n		Optional to decide with PM				
	e	a						
Approach	QnQ formulation vs the innovator or are we changing the formulation/ Design around to avoid the patent							From Patent TAB
TDP	**Innovator**			**Emcure**				
Strength	x mg	y mg	z mg	x mg	y mg	z mg		
Description:								
Shape								
Colour								
Engraving								
Packaging		PICTURE			PICTURE			Need to upload image
Primary								
Secondary								
Shelf-life								
Storage / Handling								

c) PBF charter should be business unit specific and we can have multiple in case of one molecule, if strength are different for business units.

d) We need to display data of Type of submission, National Approval & Dates in read only format, just for user to see logic begin the earliest launch date

12. Commercial Module Changes

a) We need to have another layer/tab for the country, where strength will be displayed as per country and further level / operation will be same. So eventually we will have data for every business unit -> Country -> Strength -> Pack Size -> Year Data.

b) In this module we need additional feature to extend interested countries so user can select more countries interested than what they actually selected when they shown interest in PIDF

    i. It will effect on PIDF & IPD both screens since its reverse feature

        1. IPD form will be editable to submit the data for new countries

        2. PIDF form will be editable for submit the data for new countries

c) Commercial year data --> Target cost of good (decimal field) need to be add into popup

d) Commercial year data, initially discussed to add for 3 years now we need to add for 5 years.

e) Currently we have one scheduler which send reminder everyday to those users who have access of commercial module, it will send to those users only who said interested or not taken any action.

    1. Now we need to change in logic again where reminder will be send to business unit who said interested while PIDF and this reminder frequency will be once in a week

13. API Management

a) If user select API Not Interested than User will have a form in the same popup, These are the fixed properties and it wont be dynamic

API Outsource		API Management	
API suppliers	Primary	Potential Alt. 1	Potential Alt. 2
Supplier			
Polymorph			
Process (early c)			
Process (late c)			
Manufacturing site			
Date of Site EU authority inspection	From Quality	From Quality	From Quality
Date of Site Tillomed inspection	From Quality	From Quality	From Quality
Lead time			
DMF availability			
Cost (R&D cost/KG)			
Cost (commercial cost/KG)			
	textboxes	textboxes	textboxes

b)

    1. As per this scope we only need to capture this data, we do not need to display it any where. We will consider this in next milestone.

c) If user select API Interested than User will have a form in the API RnD section, These are the fixed properties and it wont be dynamic

API Rnd & Charter (Readonly)	
API if In-house	
Root of Synthesis	
Polymorph	
Process (early c)	
Process (late c)	
Manufacturing site	
Scheduled	
Filing time	
Investments/Capex if Any	
Lead time	
Cost (R&D cost/KG)	
Cost (commercial cost/KG)	

d)

    i.   This filled data we need to present in API charter in readonly fields.

14. Finance Management

    a)   We do not required any country mapping in Batch wise costing section

    b)   We will have all the business units which is active in the system

        i.   Form will be enabled for only those business units says interested, for other business unit form will not be there we will have note : "{BusinessUnit} have said not interested on {DateTime} by {User}"

    c)   We will have all the strength from different country and business unit in one dropdown

    d)   COGS will be same in case of one SKU and pack size (for different business unit) only market share and NSP are going to change as per entered in commercial for different business unit

    e)   Finance Charter

        i.   We need feature to see summary as per business unit and country

        ii.   We need feature to see summary as per business unit and all the countries.

    f)   Currently for One SKU and Pack size we are getting some data from commercial, these data we are getting from the commercial (In commercial those are year specific), as of now we are fetching fist year data for that SKU and pack size and use for display and calculation. As discussed with SID this is correct and no changes required.

15. Budget Approval

    a) In case of different strength available for business unit, we will have different charter. If we will have same strength than we will have one charter.

    b) Finance Charter

        i. We need feature to see summary as per business unit and country

        ii. We need feature to see summary as per business unit and all the countries.

        iii. We need feature to see summary for all business unit (consolidated)

            1. Till Cumulative cash flow all the data will be sum but after that all values will be calculated from upper values only, so sum will not happen there.

    c) By Default Finance Charter should be selected as active one

    d) We need to add another data to display on this screen

        i. Market

        ii. Launch Year

        iii. Country wise summary

            1.

Molecule + Pharmaceutical form	SU (IMS Volume)			SU (IMS Volume)			SU (IMS Volume)			Launch Stock required
	Launch year			Launch year +1			Launch year +2			3, 6, 9 Months
	Selling price	Units	Value	Selling price	Units	Value	Selling price	Units	Value	
10 mg --- 1*10			=C10xD10			=F10xG10			=I10xJ10	=D10*M9/12
Strength 1 Pack size 2			=C11xD11			=F11xG11			=I11xJ11	=D11*M9/12
Strength 1 Pack size n			=C12xD12			=F12xG12			=I12xJ12	=D12*M9/12
Strength 2 Pack size 1			=C13xD13			=F13xG13			=I13xJ13	=D13*M9/12
Strength 2 Pack size 2			=C14xD14			=F14xG14			=I14xJ14	=D14*M9/12
Strength 2 Pack size n			=C15xD15			=F15xG15			=I15xJ15	=D15*M9/12
Strength n Pack size 1			=C16xD16			=F16xG16			=I16xJ16	=D16*M9/12
Strength n Pack size 2			=C17xD17			=F17xG17			=I17xJ17	=D17*M9/12
Strength n Pack size n			=C18xD18			=F18xG18			=I18xJ18	=D18*M9/12
Tradename required	Yes / No	If yes	Tradenam date register	Add in PIDF Form country wise						

16. Wishlist Module

    a) This will be simple form where we will manage CRUD operations. This data will not be utilized any where.

        i. Type drop down These will fetch from db table, but master is not required in this scope.

        ii. We will utilize this data later -> Its out of scope for now.

Note- Geography and country should be mapped together.

iii.

17. Outsourced /In-licensing products

    i.   PBF Charter (Budget Approval Screen)

        1.   We will present the data in same format as we are entering details, since there are no format available as of now.
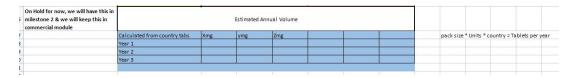
Milestone 1 - EPIC 3

18. For one time exercise requesting is the new launches tool file format which we will fill as per our new tool requirement considering new field additions

    a)   We need to have upload excel file for all steps at PIDF process, where all the data will be uploaded.

b) Excel format will be prepared by NeoSOFT, which will be as per new developed system.

c) Emcure team will add data in those Excel format provided by NeoSOFT and upload file. It will import all the data into system. All these data will be pre approved since those are existing data and pre approved only.

d) We will upload one PIDF request at a time in excel file, if there are 100 PIDF than user will upload 100 Excel file or select multiple files to upload.

    i. Excel upload PIDF Management

    ii. Excel upload IPD Management

    iii. Excel upload Medical Management

    iv. Excel upload Commercial Management

    v. Excel upload PBF Management

    vi. Excel upload Finance Management

    vii. Excel upload API Management

    viii. Task Creation / Migration in Project Management which will happen auto

Milestone 2

1. Different summary on screens

    a) Commercial Module

On Hold for now, we will have this in milestone 2 & we will keep this in commercial module		Estimated Annual Volume							
	Calculated from country tabs	Xmg	ymg	Zmg				pack size * Units * country = Tablets per year
	Year 1							
	Year 2							
	Year 3							

       i.

2. Reports