

Bernhard Hauth
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INHOUSE Supply Point Evaluations & Decisions in SANITY

SANDOZ

CONTENT

1 SPC Business Process

* key differences 'old versus new'

2 Structure in SANITY

3 Requesting SPC Submission

4 Transparency on SPC Submissions

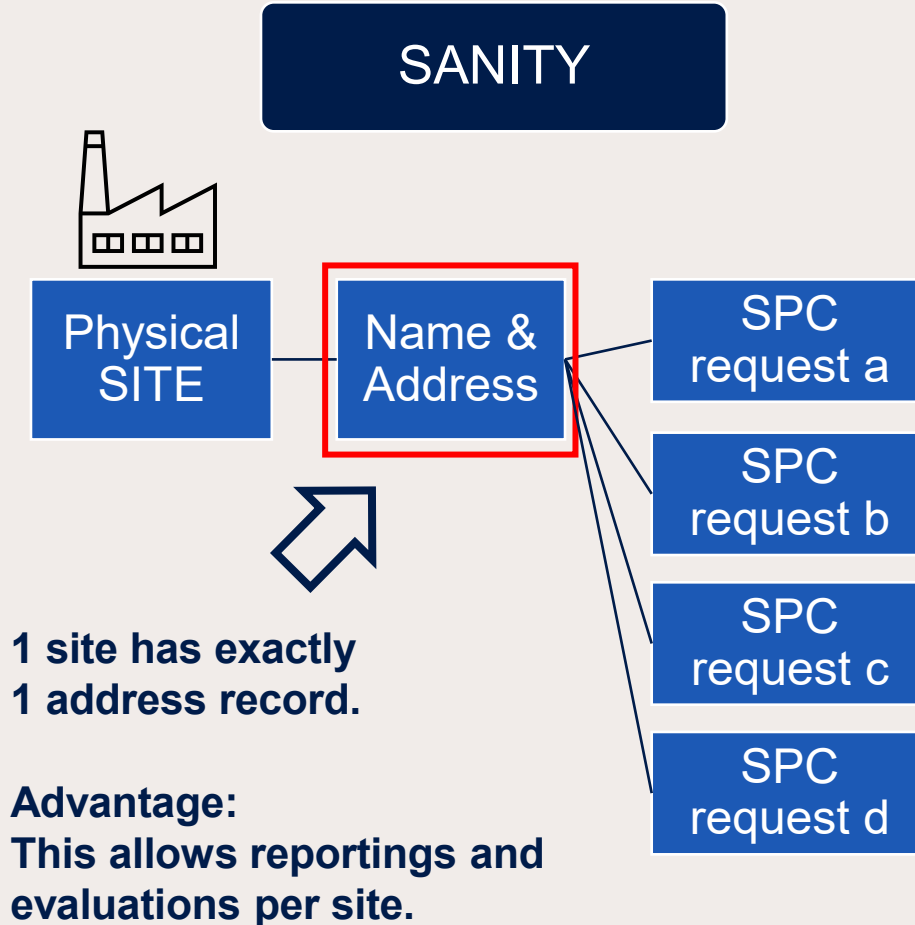
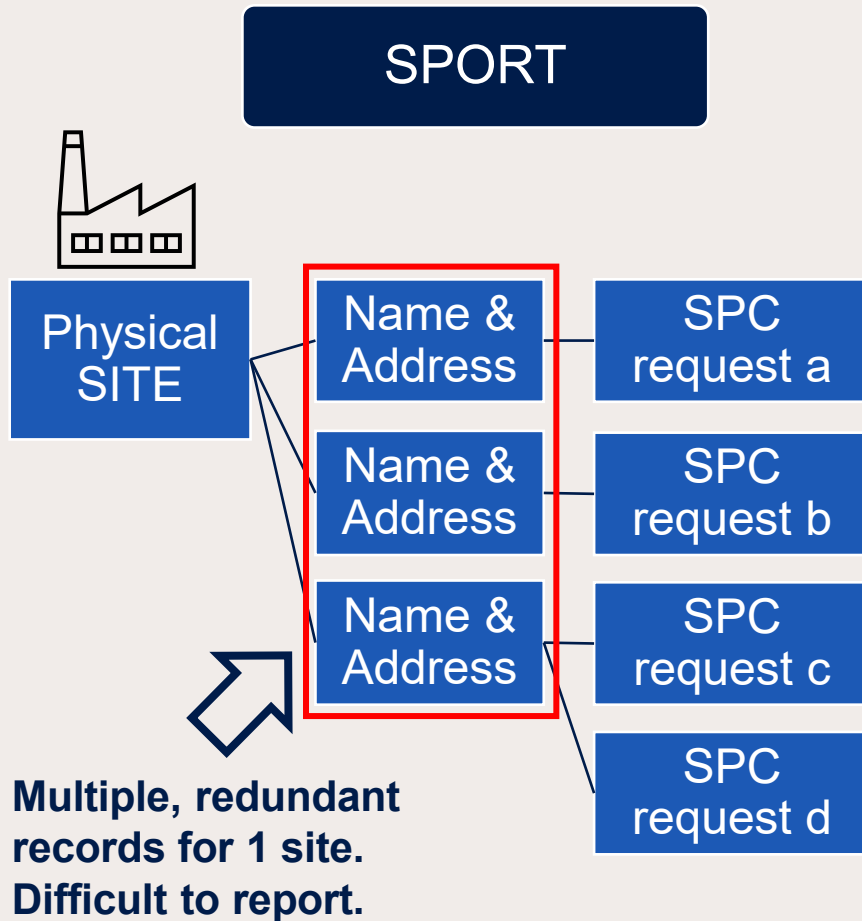
5 Evaluating SPC Submissions

6 Site Status

7 Contact Persons

SPC Business Process:

Key difference SPORT versus SANITY



CONTENT

1 SPC Business Process

2 Structure in SANITY

- * SPC Stage Gates
- * SANITY structure

3 Requesting SPC Submission

4 Transparency on SPC Submissions

5 Evaluating SPC Submissions

6 Site Status

7 Contact Persons

SPC Stage Gates in SANITY

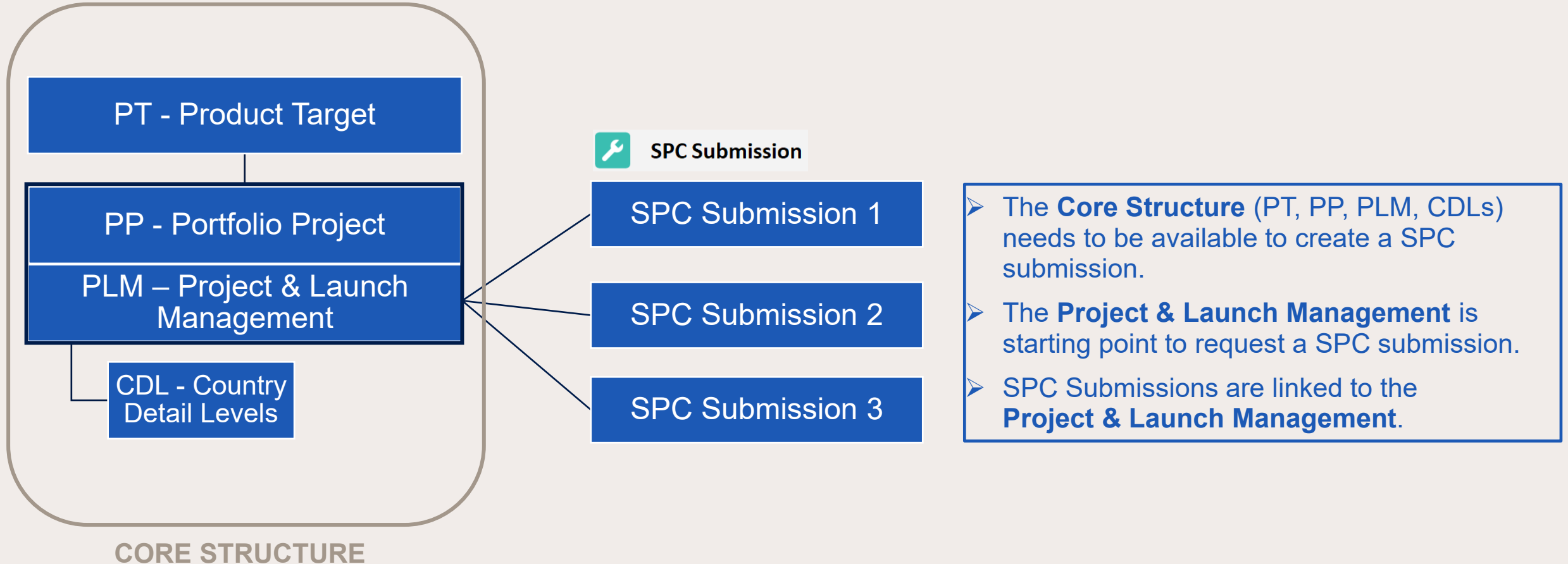


SANITY SPC Submissions STAGE GATES & RESPONSIBILITIES:



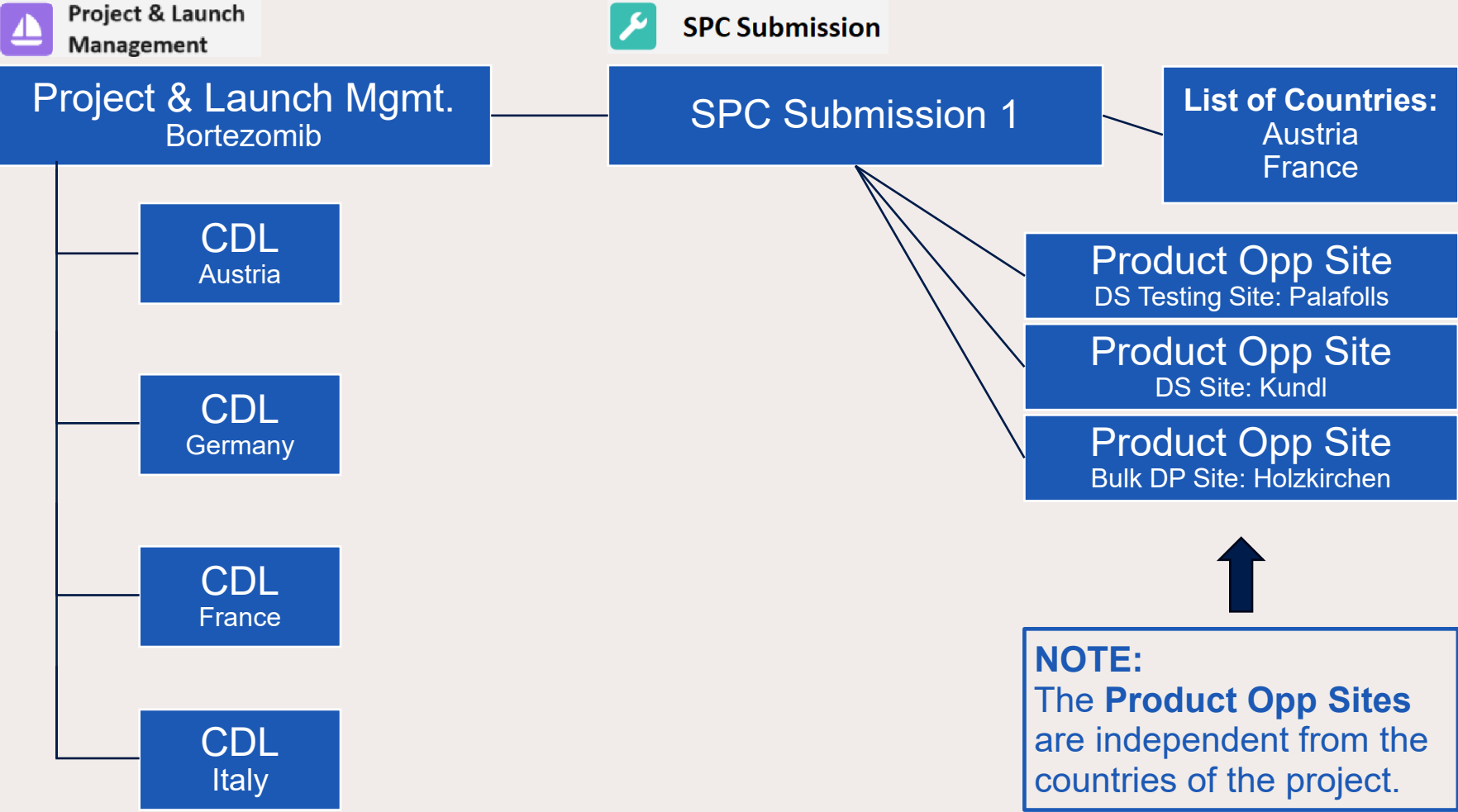
STRUCTURE IN SANITY

The SPC Submissions are linked to the PLM (Project & Launch Management)



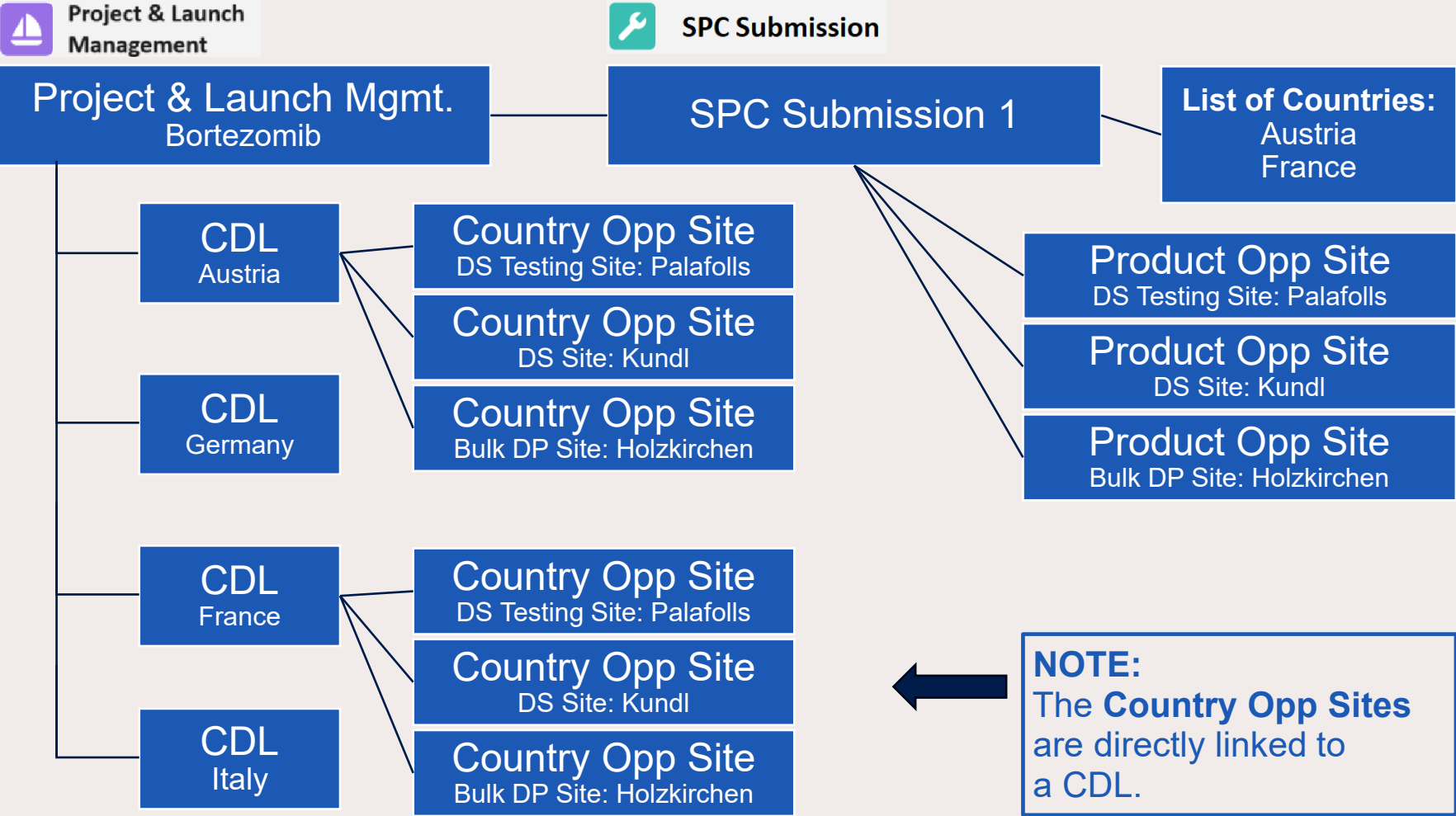
SUBMISSION

BEFORE APPROVAL: Sites are not linked to CDLs



SUBMISSION

AFTER APPROVAL: Sites are linked to CDLs



CONTENT

1 SPC Business Process

2 Structure in SANITY

3 Requesting SPC Submission

- * Requesting sites
- * Replacing a site
- * Submitting for evaluation

4 Transparency on SPC Submissions

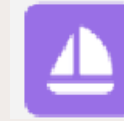
5 Evaluating SPC Submissions

6 Site Status

7 Contact Persons

How to request a SPC Submission:

Starting Point: Project & Launch Management



Project & Launch
Management

1

Open the Project &
Launch Management

2

Select
„New SPEED SPC“

The screenshot displays the Sandoz Project & Launch Management interface. At the top, a red box highlights the 'Project & Launch Management' header and the project name 'Ibuprofen FCT (302252) SDC DEHO'. To the right, a red box highlights the 'New SPEED SPC' button in the top navigation bar. Below the header, a summary row shows various metrics: Overall Traffic Light, Active Pre-Launch Countries (0), Launched Countries (4), Country Status Blank (25), Interest Stage Blank (35), and Country Stages (Approved, In Registration, Launched, Active). The main content area has tabs for Details, Project Timeline, [In-House] Budget, Team, and [In-House] SPC Submissions. The [In-House] SPC Submissions tab is active, showing a list of SPC submissions. A modal window titled 'Speed SPC Wizard' is open, displaying a progress bar and the text 'New SPEED SPC request'. The modal also shows product details: Product API : Bortezomib, Dosage Form : LYVI, and Project Strengths : 3 mg LYVI. A large blue arrow points from the 'New SPEED SPC' button to the 'Speed SPC Wizard' modal.

Project & Launch Management
Ibuprofen FCT (302252) SDC DEHO

Request Forecast Update Cancel Forecast Requests Edit Request Feedback **New SPEED SPC**

Overall Traffic Light Active Pre-Launch Countries 0 Launched Countries 4 Country Status Blank 25 Interest Stage Blank 35 Country Stages Approved, In Registration, Launched, Active

Details Project Timeline [In-House] Budget Team [In-House] SPC Submissions

SPEED SPC Submissions (0)

Selected Sites & Scopes (No Countries) (0)

Sites & Scopes & Countries (0)

Speed SPC Wizard

New SPEED SPC request

Product API : Bortezomib
Dosage Form : LYVI
Project Strengths : 3 mg LYVI

3

SPC Wizard
opens

SPEED SPC Wizard

Step 1: New SPEED SPC request

Speed SPC Wizard

Progress: New SPEED SPC request (active), Countries Selection, Selected Countries, Scopes Selection, SPC Request Creation

Product API : Ibuprofen
Dosage Form : FCT
Project Strengths : 200 mg FCT; 400 mg FCT; 600 mg FCT; 800 mg FCT

* Submission Type
New Launch

* Request Driver
Portfolio Development

* Request Rational
field: Request Rational

* Background
field: Request Rational

* Proposed Timeline
field: Proposed Timeline

Comments
field: Comments

Close

Next

To skip the wizard without saving.

Mandatory to select one of the 4 options:

- New Launch
- Supply Chain Change
- Tech Transfer
- Scope Extension

Move to next step.

SPEED SPC Wizard

Step 2: Country Selector

Speed SPC Wizard

Close

New SPEED SPC request Countries Selection Selected Countries Scopes Selection SPC Request Creation

Select Region

All (3 of 40)

Add All Remove All

Select Countries

Available countries

Armenia (AM)

Belgium (BE)

Benin (BJ)

Bosnia and Herzegovina (BA)

Botswana (BW)

Bulgaria (BG)

Burkina Faso (BF)

Selected Countries

Italy (IT)

Greece (GR)

Austria (AT)

Previous Next

Select region to make the number of available countries easier to handle

Mark the countries first, then you can select or de-select them

Marked countries can be sorted using these arrows

SPEED SPC Wizard

Step 3: Selected Countries

Speed SPC Wizard

Close

Progress bar steps: New SPEED SPC request, Countries Selection, **Selected Countries**, Scopes Selection, SPC Request Creation

Selected Countries

Europe : Portugal (PT),Romania (RO),Slovakia (SK),Slovenia (SI),Spain (ES)

NAmer : United States (US)

Previous

Next

Change needed? ,Previous' brings you back to step 2.

Useful to x-check your selection

In the next step, you can specify the sites

SANDOZ

SPEED SPC Wizard

Step 4: Scopes Selection

Speed SPC Wizard

Close

✓

✓

✓

New SPEED SPC request

Countries Selection

Selected Countries

Scopes Selection

SPC Request Creation

Site Scopes	Replacement	New Proposed Sites	Site to be Replaced
DS Site	<input type="checkbox"/>	<div><div>Search..</div><div><div>Sandoz Pharmaceuticals SRL - 2049780</div><div>×</div></div></div>	
DS Testing Site	<input type="checkbox"/>	<div><div>Search..</div><div>blank</div></div>	
DS Stability Site	<input type="checkbox"/>	<div><div>Search..</div><div>blank</div></div>	
Bulk DP Site	<input type="checkbox"/>	<div><div>Search..</div><div>blank</div></div>	
DP Testing Site	<input checked="" type="checkbox"/>	<div><div>Search..</div></div>	<div><div>Search..</div></div>
Primary Packaging Site	<input type="checkbox"/>	<div><div>Search..</div><div>blank</div></div>	

Use the search field to find the appropriate site

Leave blank, if Scope is not part of request.

If ,Replacement' is checked, then the search field ,Site to be replaced' needs to be populated.

Check in case of Replacement


SPEED SPC Wizard

Step 5: SPC Request Creation

To skip the wizard without saving.

The screenshot shows the 'Speed SPC Wizard' window. At the top left, the title 'Speed SPC Wizard' is displayed. Below it is a progress bar with five steps: 'New SPEED SPC request', 'Countries Selection', 'Selected Countries', 'Scopes Selection', and 'SPC Request Creation'. The first four steps are marked with a blue checkmark, indicating they are completed. The fifth step, 'SPC Request Creation', is marked with a blue circle, indicating it is the current step. Below the progress bar, the text 'Please proceed for creating the SPEED SPC Submission' is displayed. In the top right corner, there is a red 'Close' button. In the bottom right corner, there is a blue 'Finish' button.

To create the SPC request in SANITY.

 SPC Submission

[SPC00000195] Ibuprofen FCT [New Launch]

SPC Stage Gate
SPEED

Submission Type
New Launch

Submission Subtype

SPEED Evaluation Lead

SPEED

Follow-Up Activities

Approved

R

Request Information

General Information

SPC Submission Name

[SPC00000195] Ibuprofen FCT [New Launch]

Product API & Dosage Form

Ibuprofen FCT

Project Strength(s)

200 mg FCT; 400 mg FCT; 600 mg FCT; 800 mg FCT

SPC Stage Gate

SPEED

SPEED Requestor

Global In-House SPC Requestor BIO & SM Test User

SPEED Evaluation Lead

Submission Information

Request Rational

field: Request Driver

Request Driver

Portfolio Development

Background

field: Request Rational

Proposed Timeline

field: Proposed Timeline

Comments

field: Comments

Countries

Countries in Selection

Italy (IT);Greece (GR);Austria (AT);Paraguay (PY);

Submission Type

SPC Stage Gate

Text fields from Wizard

Selected Countries

16 Business Use Only

SANDOZ

SPC Submission



SPC Submission

SPC Submission

[SPC00000195] Ibuprofen FCT [New Launch]

> Countries

Financials & Timelines

Financials

Launch + 5 Yr Net Sales

USD 0.00

Target Launch(es)

Target Regulatory Submission(s)

First Technical Batch Date

Request Assignment Date

First Patent Expiration

Planned Implementation Date

Scopes (Roles)

DS Site

Under Evaluation

Bulk DP Site

Unchanged / Not Requested

DS Testing Site

Unchanged / Not Requested

DP Testing Site

Unchanged / Not Requested

DS Stability Site

Unchanged / Not Requested

Primary Packaging Site

Unchanged / Not Requested

Secondary Packaging Site

Unchanged / Not Requested

Release Site

Unchanged / Not Requested

DP Stability Site

Unchanged / Not Requested

Import Testing Site

Unchanged / Not Requested

Device Assembly Site

Unchanged / Not Requested

Sterilization Site

Unchanged / Not Requested

please use the sections below to see the sites and select/reject the ones where multiple sites are indicated for the same scope (role)

Sites Under Evaluation (multiple sites for same scope need selection) (1)

1 item • Filtered by Site Status • Updated a few seconds ago

Product Opp Site Link

Site Role

Replacement Site

Site Status

Site Comm...

1

DS Site: Sandoz Pharmaceuticals SRL - 2049780

DS Site

Under Evaluation

View All

Selected Sites (0)

Rejected Sites (0)

Financial information from Portfolio Management


Scopes selected in Wizard

Use this section to select / reject sites, if you have multiple sites per scope under evaluation

SPC Submission

Adding Sites

You can add Sites
for further Scopes
to the same Submission

 SPC Submission

[SPC00000195] Ibuprofen FCT [New Launch]

+ Follow

Add Site

Submit for Evaluation

SPC Stage Gate	Submission Type	Submission Subtype	SPEED Evaluation Lead	
SPEED	New Launch			

SPEED

Follow-Up Activities

Approved

Rejected


Stopped

SPC Submission

Prepare to Submit for Evaluation




SPC Submission






 SPC Submission

[SPC00000195] Ibuprofen FCT [New Launch]


[+ Follow](#) [Add Site](#) [Move To Follow-Up Activities](#)



Project Strength(s)	i 200 mg FCT; 400 mg FCT; 600 mg FCT; 800 mg FCT	SPEED Evaluation Lead	
		Owner	Evaluation Leads 


▼ Submission Information

Request Rational	field: Request Driver 	Background	field: Request Rational 
Request Driver	Portfolio Development 	Proposed Timeline	field: Proposed Timeline 
		Comments	field: Comments 

▼ Attachment Acknowledgement

Attachment Acknowledgement
☒ 

 **Files (1)** 

 [forecast for SPC submission](#)
21-May-2025 • 18KB • pdf

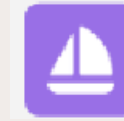
[View All](#)

Prior to submission, you need to

- Upload the file(s) with forecast information
- Flag the checkbox 'Attachment Acknowledgement'

SPC Submission

Where to find the Forecast information



Project & Launch
Management

Project & Launch Management

SDC SILJ

Created by Matthew Bohman, 22:11

Country Status Blank

Molecule

Project POS

NPV

IRR %

Financial Project Close Out

GloRIA Override

Country Stages

Quip URL

PLM responsible(s)

PLM ID

Unique ID

Tentative approval / IP Hold, In Evaluation, Active, Discontinued, Approved, In Registration, Evaluated

Owner: Antonio Vujicic, PM: Antonio Vujicic

PLM-416078-01

416078

Speed Forecasting Information

Sum of Forecast Net Sales (converted)

Forecast Country

- CA Canada
- CL Chile
- HK Hong Kong
- AU Australia
- CH Switzerland
- DK Denmark
- EE Estonia
- ES Spain
- FR France
- IE Ireland
- IT Italy
- LT Lithuania
- LV Latvia

Year

View Report

As of Today at 18:19

Yearly Launch Information


Click on **View Report** to be able to download as excel file.

After downloading the report as excel file, please delete all countries in the excel file which do not belong to your SPC Submission.

SPC Submission

Submitting for Evaluation

‘Submit for Evaluation’ hands the submission over to the SPC Manager for evaluation. Evaluators and Requestors will receive an email notification.

 SPC Submission

[SPC00000195] Ibuprofen FCT [New Launch]

+ Follow

Add Site

Submit for Evaluation

SPC Stage Gate	Submission Type	Submission Subtype	SPEED Evaluation Lead
SPEED	New Launch		

The request has been submitted for evaluation and is now under the responsibility of the evaluators.

SPEED


Follow-Up Activities

Approved

Rejected

Stopped

The action button changes from ‘Submit for Evaluation’ into ‘Move To Follow-Up Activities’, and the orange message on the SPC Submission indicates the change of responsibilities.

 SPC Submission

[SPC00000206] Acetylcysteine POS [New Launch]

+ Follow

Add Site

Change Owner

Move To Follow-Up Activities

SPC Stage Gate	Submission Type	Submission Subtype	SPEED Evaluation Lead
SPEED	New Launch		

SPEED

Follow-Up Activities


Approved

Rejected

Stopped

Project & Launch Management

Where to find Sites & Submissions

 Project & Launch Management
Acetylcysteine POS (301998) SDC
DEHO

[Request Forecast Update](#) [Cancel Forecast Requests](#)


Details

Project Timeline

[In-House] Budget

[In-House] Supply Chain

More ▾

 **SPEED SPC Submissions (4)**

4 items • Filtered by Record Type • Updated vor ein paar Sekunden

SPC Submission ... ▾

SPC Stage Gate ▾

Countries i... ▾

SPEED Requestor ▾

SPEED Evaluatio

1	[SPC00000139] Acetyl...	Approved	Austria (AT);	Global In-House SPC R...	Bernhard Hauth
2	[SPC00000154] Acetyl...	Approved	Algeria (DZ);Port...	Global In-House SPC R...	Bernhard Hauth
3	[SPC00000157] Acetyl...	Approved	Greece (GR);Hu...	Global In-House SPC R...	Global In-House
4	[SPC00000194] Acetyl...	SPEED	Austria (AT);Bela...	Global In-House SPC R...	

View All


Sites and Scopes per Country

Record Count

Site Scope

DS Site

Import Testing Site



Country	DS Site	Import Testing Site
Algeria	1.0	0.0
Greece	1.0	1.0

All SPC Submissions with Stage Gate

If you want to filter for certain SPC Stage Gates, you can use 'View All'

Graphical representation for quick overview

Project & Launch Management

Where to find Sites & Submissions



Project & Launch
Management

Project & Launch Management
Acetylcysteine POS (301998) SDC DEHO

Request Forecast Update

Cancel Forecast Requests

Edit

Create Risk & Issue

New SPEED SPC

Initiate

Details

Risks & Issues

Team

Project Timeline

Assessments

[In-House] Budget

[In-House] Supply Chain

Countries & Fcsts

More ▾

SPEED SPC Submissions (5)

5 items • Filtered by Record Type • Updated 4 minutes ago

Sites & Scopes & Countries (10+)

10+ items • Updated a few seconds ago

	SPC Country Opp S...	SPC Country Opp Site: Site Name	SPC Country O...	SPC Count...	SPC Count...	SPC Country Opp Site: SPC Submission	
1	SPC-Country-Site-00366	Hexal AG - 2045908	DS Site	Austria	Effective	[SPC00000139] Acetylcysteine POS [New Launch]	▾
2	SPC-Country-Site-00367	Sandoz Private Limited (Kalwe) - 1073	DS Testing Site	Austria	Effective	[SPC00000139] Acetylcysteine POS [New Launch]	▾
3	SPC-Country-Site-00348	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Spain	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]	▾
4	SPC-Country-Site-00349	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Romania	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]	▾
5	SPC-Country-Site-00350	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Algeria	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]	▾
6	SPC-Country-Site-00351	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Portugal	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]	▾
7	SPC-Country-Site-00352	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Slovenia	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]	▾
8	SPC-Country-Site-00353	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Slovakia	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]	▾
9	SPC-Country-Site-00354	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Spain	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]	▾
10	SPC-Country-Site-00355	Sandoz Pharmaceuticals SRL - 2049780	DS Site	Romania	Effective	[SPC00000154] Acetylcysteine POS [Supply Change]	▾

View All

To see this table, please scroll down in ,[In-House] Supply Chain‘

Link opens the SPC Submission



CONTENT

- 1 SPC Business Process
- 2 Structure in SANITY
- 3 Requesting SPC Submission

4 Transparency on SPC Submissions

- * Choosing the right APP
- * List Views with SPC Submissions

- 5 Evaluating SPC Submissions
- 6 Site Status
- 7 Contact Persons

Supply Point Evaluation & Decision: Choosing the right APP



In-House Supply
Point Evaluations

1

SANITY

Hover with your
mouse over
the 9 dots

Welcome to SANITY

Home

Das

App Launcher

supply

2

Type ,supply' in search field

Apps



Supply Point Evaluation & Decision


3



In-House Supply Point Evaluations

Select In-House
Supply Point APP

Supply Point Evaluation & Decision: Finding the SPC Submissions

In-House Supply Po...

HomeAccountsProject & Launch ManagementSPC Submissions

Search...

SPC Submissions

Open Requests Assigned to Me

1 item • Sorted by SPC Submission Name • Filtered by My spc submissions - Record Type, SPC Stage Gate • Updated a few seconds ago

	SPC Submission Name ↑	Product Opportunity	Prod...	SPC ...	Submission...	Sub...	Created By
1	[SPC00000174] citrin -X LDP [Supply Change]	citrin -X LDP- Sandoz Dev		SPEED	Supply Change		Global In-House SPC Manager BIO &

SPC Submissions

All Requests Submitted for Evaluation

3+ items • Sorted by SPC Submission Name • Filtered by Evaluation Leads - Record Type, Owner Alias • Updated a few seconds ago

	SPC Submission Name ↑	Product Opportunity	Product API & Dosage Form	Pro...	Submissio..
1	[SPC00000160] Zolpidem tartrate FCT [Supply Change]	Zolpidem tartrate FCT- SDC DEHO	Zolpidem tartrate FCT		Supply Char
2	[SPC00000189] Glucosamine hydrochloride ASP [Supply Change]	Glucosamine hydrochloride ASP- SDC INHY	Glucosamine hydrochloride ASP		Supply Char
3	[SPC00000190] Iron gluconate APW [Supply Change]	Iron gluconate APW- SDC DEHO	Iron gluconate APW		Supply Char

SPC Submissions

All Requests Under Evaluation

3 items • Sorted by SPC Submission Name • Filtered by All spc submissions - Record Type, SPEED Evaluation Lead, Assigned For Evaluation • Updated a few seconds ago

	SPC Submission Name ↑	Product Opportunity	Product API & Dosage F...	Produc...	Submission ...
1	[SPC00000188] Vonoprazan fumarate FCT [New Launch]	Vonoprazan fumarate FCT- SDC ATKU	Vonoprazan fumarate FCT		New Launch
2	[SPC00000192] Iron gluconate APW [Tech Transfer]	Iron gluconate APW- SDC DEHO	Iron gluconate APW		Tech Transfer
3	[SPC00000193] Acetylcysteine GOSO [Tech Transfer]	Acetylcysteine GOSO- SDC DEHO	Acetylcysteine GOSO		Tech Transfer

SPC Submissions

All Approved Requests

3+ items • Sorted by SPC Submission Name • Filtered by All spc submissions - Record Type, SPC Stage Gate • Updated a few seconds ago

You are the **Evaluation Lead** of these SPC Submissions

All Submissions which are not assigned yet to an **Evaluation Lead**

All Submissions which are assigned to an **Evaluation Lead**

CONTENT

- 1 SPC Business Process
- 2 Structure in SANITY
- 3 Requesting SPC Submission
- 4 Transparency on SPC Submissions


5 Evaluating SPC Submissions

- * Taking ownership
- * Evaluation
- * Closing the SPC Submission

6 Site Status

7 Contact Persons

Supply Point Evaluation & Decision: Finding the SPC Submission



In-House Supply Po...

HomeAccounts▼Opportunity Detail & Diligences▼SPC Submissions▼

Search...

1

2

3

SPC Submissions

All▼

2 items • Sorted by Requested SPC date • Filtered by All spc submissions - Record Type • Updated 7 minutes ago

Open in Quip

SPC Template Multi Re

acetylcy

3

Business Timing View

Requested SPC date

	<div>SPC Submission Name</div>	<div>Record Type</div>
1	<div><input type="checkbox"/> [SPC00000154] Acetylcysteine POS [Supply Change]</div>	SPEED SPC Submission
2	<div><input type="checkbox"/> [SPC00000139] Acetylcysteine POS [New Launch]</div>	SPEED SPC Submission

Select SPC Submissions

Search for API

Open the SPC Submission

SPC Submission Record:

Take ownership by changing the owner



SPC Submission

Change the owner

SPC Submission

[SPC00000195] Ibuprofen FCT [New Launch]

+ Follow

Add Site

Change Owner

Move To Follow-Up Activities

SPC Stage Gate

SPEED

Submission Type

New Launch

Submission Subtype

SPEED Evaluation Lead

SPEED

Follow-Up Activities

Approved

Rejected

Stopped

Request Information

General Information

SPC Submission Name

[SPC00000195] Ibuprofen FCT [New Launch]

Product API & Dosage Form

Ibuprofen FCT

Project Strength(s)

200 mg FCT; 400 mg FCT; 600 mg FCT; 800 mg FCT

SPC Stage Gate

SPEED

SPEED Requestor

Global In-House SPC Requestor BIO & SM Test User

SPEED Evaluation Lead

Owner

Evaluation Leads

SANITY Linked Items

Project & Launch Management

Ibuprofen FCT (302252) SDC DEHO

Product Opportunity

Ibuprofen FCT- SDC DEHO

Portfolio Project

Ibuprofen FCT (302252)

Attachment Acknowledgement


NOTE:
A mail notification gets automatically sent to the SPEED Evaluation Lead.

Fields get updated automatically

29 Business Use Only

SANDOZ

SPC Submission Record: Submission Information


 SPC Submission

[SPC00000206] Acetylcysteine POS [New Launch]

SPC Stage Gate
SPEED

Submission Type
New Launch

Submission Subtype

SPEED Evaluation Lead
 [Global In-House SPC Manager BIO & SM TestUser](#)

SPEED

Follow-Up Activities


Approved

Request Information


General Information

SPC Submission Name


[SPC00000206] Acetylcysteine POS [New Launch]



Product API & Dosage Form

 Acetylcysteine POS


Project Strength(s)

 100 mg POS; 200 mg POS


SPC Stage Gate

SPEED



SPEED Requestor

 [Global In-House SPC Manager BIO & SM TestUser](#)

SPEED Evaluation Lead

 [Global In-House SPC Manager BIO & SM TestUser](#)


Owner

 [Global In-House SPC Manager BIO & SM TestUser](#) 

Submission Information


Request Rational

field: Request Rational




Request Driver

Portfolio Development




Background

field: Background




Proposed Timeline

field: Proposed Timeline




Comments

field: Comments




Values provided
in Wizard

SPC Submission: Selecting a Scope for evaluation

 SPC Submission

[SPC00000206] Acetylcysteine POS [New Launch]

 **Sites Under Evaluation (multiple sites for same scope need selection) (4)**

4 items • Filtered by Site Status • Updated a few seconds ago

Product Opp Site Link

Site Role


Replaceme...


Site Status

Site Comm...

1	DS Site: Medical-Sanitary Public Institution - T	DS Site	Under Evaluation	
2	DS Site: SANDOZ PRIVATE LIMITED - 2066169	DS Site	Under Evaluation	
3	DP Testing Site: WESSLING Hungary Kft - T	DP Testing Site	Under Evaluation	
4	DS Site: WUHAN GRAND HOYO - TMP-4464	DS Site	Under Evaluation	

View All


 **Selected Sites (0)**


 **Rejected Sites (0)**

Select Site to
change status

Product Opp Site:

Decision made through Status change

 Product Opp Site
SANDOZ PRIVATE LIMITED - 2066169Edit


Site Status ⓘ	Under Evaluation 	Product Opportunity	Acetylcysteine POS- SDC DEHO -3
Replacement Site		SPC Submission	[SPC00000206] Acetylcysteine POS [New Launch]
Site Role ⓘ	DS Site		




- Available Options:
- Under Evaluation
 - Selected
 - Rejected

SPC Submission record: Review your decisions



SPC Submission




 SPC Submission
[SPC00000206] Acetylcysteine POS [New Launch]

 **Sites Under Evaluation (multiple sites for same scope need selection). (2)**  

2 items • Filtered by Site Status • Updated a few seconds ago

	Product Opp Site Link	Site Role	Replaceme...	Site Status	Site Comm...
1	DS Site: Medical-Sanitary Public Institution - T	DS Site		Under Evaluation	
2	DS Site: WUHAN GRAND HOYO - TMP-4464	DS Site		Under Evaluation	




View All

 **Selected Sites (1)**  

1 item • Filtered by Site Status • Updated a few seconds ago

	Product Opp Site Link	Site Role	Replaceme...	Site Status	Site Comm...
1	DP Testing Site: WESSLING Hungary Kft - T	DP Testing Site		Selected	

View All

 **Rejected Sites (1)**  

1 item • Filtered by Site Status • Updated a few seconds ago

	Product Opp Site Link	Site Role	Replaceme...	Site Status	Site Comm...
1	DS Site: SANDOZ PRIVATE LIMITED - 2066169	DS Site		Rejected	

View All

MULTIPLE SITES PER SCOPE

- In SPC Stage **SPEED**, multiple sites for 1 scope are allowed
- If you select 1 of these sites, then all other sites of same scope are automatically 'rejected'

SPC Submission record: Stage ,Follow-Up Activities‘



SPC Submission

Next, you need to change the SPC Stage into Follow-Up Activities.

SPC Submission
[SPC00000206] Acetylcysteine POS [New Launch]

+ Follow

Add Site

Change Owner

Move To Follow-Up Activities

SPC Stage Gate
SPEED

Submission Type
New Launch

Submission Subtype

SPEED Evaluation Lead

Global In-House SPC Manager BIO & SM TestUser

SPEED

Follow-Up Activities

Approved

Rejected

Stopped

! Pre-requisite is to have maximum 1 site per site scope !

SPC Submission

Close

Please note that the SPC Stage Gate will be moved to Follow-Up Activities.


2

Finish

SPC Submission record: Stage ,Follow-Up Activities‘

In Stage **Follow-Up Activities**,

- You can change the Submissions Information
- You can not change the site selections any more

 SPC Submission

[SPC00000206] Acetylcysteine POS [New Launch]

SPEED

Follow-Up Activities

Approved

Request Information

Evaluation Information

Team

Follow-Up Activities

General Information

SPC Submission Name

[SPC00000206] Acetylcysteine POS [New Launch]

Product API & Dosage Form

Acetylcysteine POS

Project Strength(s)

100 mg POS; 200 mg POS

SPC Stage Gate

Follow-Up Activities

SPEED Requestor

Global In-House SPC Manager BIO & SM TestUser

SPEED Evaluation Lead

Global In-House SPC Manager BIO & SM TestUser

Owner

Global In-House SPC Manager BIO & SM TestUser

Submission Information

Request Rational

field: Request Rational

Background

field: Background

Request Driver

Portfolio Development

Proposed Timeline


field: Proposed Timeline

Comments

field: Comments

Submission
Information

Supply Point Evaluation & Decision: Closing the SPC Submission

 SPC Submission
[SPC00000206] Acetylcysteine POS [New Launch]

+ Follow

Change Owner

Close the SPC Submission

SPC Stage Gate


Submission Type

Submission Subtype

SPEED Evaluation Lead

Follow-Up Activities

New Launch

 Global In-House SPC Manager BIO & SM TestUser

SPEED

Follow-Up Activities

Approved

Rejected

Stopped

 Close SPC Submission

Close

Please select a final stage, and please note that you will not be able to move the stage back after the closure.

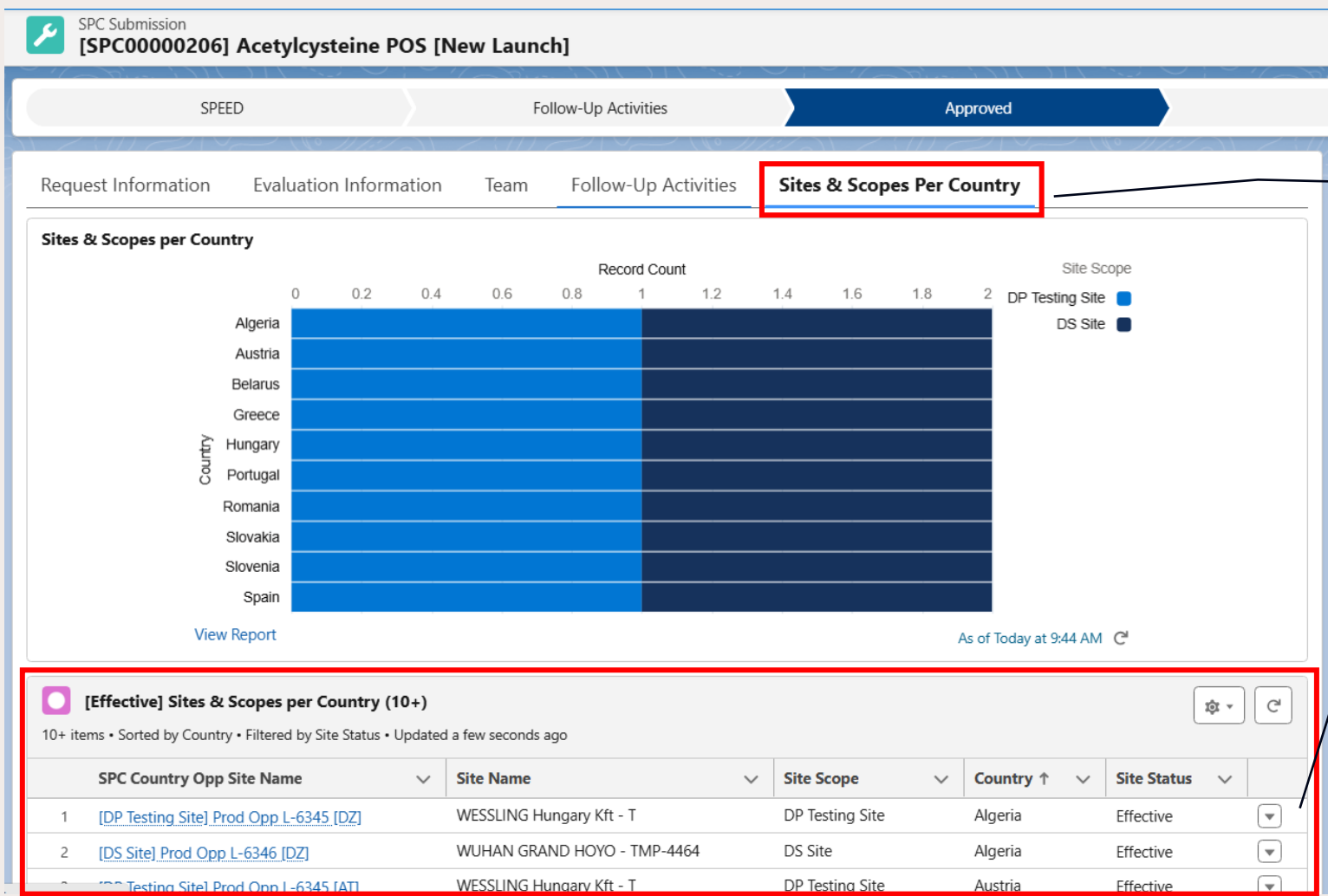
☐ **Approved** — The request is approved and all the selected sites in the background will be created for each country in scope for the submission.

☐ **Rejected** — The request is negatively closed with the with no further actions and no site record created in the background.

☐ **Stopped** — The request is negatively closed with the with no further actions and no site record created in the background.

Finish

SPC Submission: Sites & Scopes Per Country



This navigation item gets generated during approval

Note:
In the approval step, new records will be generated for each site, site scope and country.

List with 1 record per site, site scope and Country

CONTENT

- 1 SPC Business Process
- 2 Structure in SANITY
- 3 Requesting SPC Submission
- 4 Transparency on SPC Submissions
- 5 Evaluating SPC Submissions

6 Sites

- * Possible values for Site Status
- * Requesting a new Site

7 Contact Persons

Sites Status

Possible values



Manually selectable Site Status

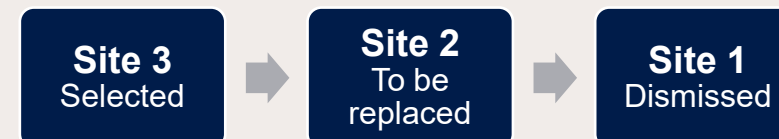
- Under Evaluation
- Selected
- Rejected

A screenshot of a web application interface for 'Product Opp Site'. The header shows the site name 'Novartis Pharma Services Inc. - 2070543'. Below the header, there are three rows of data. The first row, 'Site Status', is highlighted with a red border and shows the value 'Under Evaluation'. The second row, 'Replacement Site', is empty. The third row, 'Site Role', shows the value 'Release Site'. Each row has an edit icon (pencil) on the right side.

Product Opp Site	
Novartis Pharma Services Inc. - 2070543	
Site Status ⓘ	Under Evaluation
Replacement Site	
Site Role ⓘ	Release Site

Automatically assigned Site Status

- Effective
This is the status right after approval.
It is not intended to replace this first site yet.
- To be replaced
If a new site has been selected, then the first site moves into 'To be replaced'.
- Dismissed
If a third site replaces the second site, then the first site moves into 'Dismissed'.



Sites



Product Opp Site

If a site is not available in SANTY

You can request the creation of a Site from the SANITY support team

Following information is required

- Account Name (Company Name)
- Billing Street
- Billing City
- Billing Zip/Postal Code
- Billing Country

Mail to: sanity.support@sandoz.net

CONTENT

- 1 SPC Business Process
- 2 Structure in SANITY
- 3 Requesting SPC Submission
- 4 Transparency on SPC Submissions
- 5 Evaluating SPC Submissions
- 6 Site Status

7 Contact Persons

- * Help to identify the right project
- * Help to setup a new site in SANITY

SPC Submission - Contact Persons

PROJECTS

Global Commercial Operations Team

- ✓ Help to identify the right project in SANITY
- ✓ Creating new projects in SANITY
- Nancy Kapoor, nancy-1.kapoor@sandoz.net
- Santhos Itikyal, santhosh_reddy.itikyala@sandoz.com

SANITY USAGE

Training Manager, SANITY Support Team

- ✓ Help how to use SANITY
- ✓ Technical challenges in SANITY
- ✓ Creating new projects in SANITY
- Bernhard Hauth, hauthbe3@sandoz.net
- sanity.support@sandoz.net

SITES

SANITY Support Team

- ✓ Providing extracts from SANITY
- ✓ To create a new site in SANITY

Important: Validation, if the site does not exist yet in SANITY, must be done before requesting the support team.

- sanity.support@sandoz.net

Following site information is required

- Account Name (Company Name)
- Billing Street
- Billing City
- Billing Zip/Postal Code
- Billing Country

SANDOZ