

Deploying GxP Cloud Solutions-

Lessons from the frontline



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Deploying GxP Cloud Solutions

The presenter & the company...

Ray McKinney

Director, US West Coast Operations

- B.Eng (Mechanical Engineering)
- MBA (Finance)
- Lean Six Sigma (Black Belt)

Computer systems compliance since 1995
Quality Systems & manufacturing focus

Resident of Oakland, CA
Native of Glasgow, Scotland

NNIT

- Pre-1994: IT department of Novo Nordisk
- 1994: NNIT created as independent profit-center
- 1998: NNIT A/S incorporated as separate legal entity
- 2005: 500 employees milestone reached
- 2006: Offices in China & Czech Republic open
- 2007: 1000 employees
- 2009: Acquisition in Philippines completed
- 2012: NNIT Inc. opens in USA
- 2015: NNIT listed on NASDAQ OMX
- 2018: Acquisition of Valiance Partners (data migration services)
- 2020: 3000+ employees

We have GxP in our DNA.
Life sciences IT specialists.

Deploying GxP Cloud Solutions

Assumptions

Attendees assumed to have a basic knowledge of...

- Main economic arguments SaaS / Hosted v On-Premise
- Core architectural arrangements (SaaS / PaaS / IaaS etc.)
- Computer Systems Validation (CSV) fundamentals
- Operations & Maintenance requirements

for GxP computer systems.

Deploying GxP Cloud Solutions-

Lessons from the frontline

What SaaS firms say:

"You focus on finding drugs, we'll take care of the software and the hosting"



What some pharma execs hear:

"Great!
They will take care of the compliance work.
It's their job now, not ours."

"...the tragedy begins, not when there is misunderstanding about words, but when silence is not understood."

Henry David Thoreau

Deploying GxP Cloud Solutions

The short version...



A new paradigm requires rethinking your processes...

What worked for on-premise hosting, will not always work for SaaS.

Re-map your system lifecycle for SaaS applications / vendors...

Don't assume! Document your relationship with SaaS vendors.

Why are we discussing this subject?

Is this just another consultants' scare story?



Lack of documentation (or access to documentation) of qualification activities:

Recent inspection findings relating to the qualification and validation of computerised systems are of concern, as some sponsors have not been able to provide adequate documentation of the required qualification and validation activities for computerised data collection tools/software during inspections. Computerised systems used in clinical trials can be built by the sponsor but are more typically purchased from a vendor either under a license to use software or as part of a service purchased, which could also include e.g. trial specific builds, hosting of trial data, etc. Qualification activities would consequently be performed by the sponsor or the vendor.

Insufficient contractual arrangements:

Clear, written agreements should be in place to document any arrangements between the sponsor and the vendor with regards to qualification and validation. The sponsor remains responsible for ensuring that the conduct of the trial and the final data and data that are submitted to support an MAA comply with relevant legislation.

If appropriate contracts cannot be put in place, e.g. because a vendor does not allow provision of adequate measures as listed above (access to system requirements specifications, pre-qualification audits, access for GCP inspectors, etc.) and set out in Q&A # 8, systems from such a vendor shall not be used in clinical trials. This is irrespective of the number of sponsors

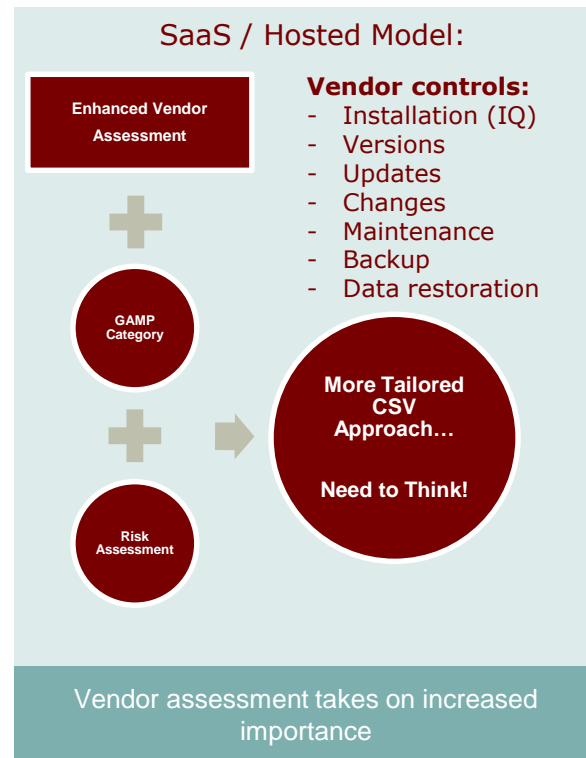
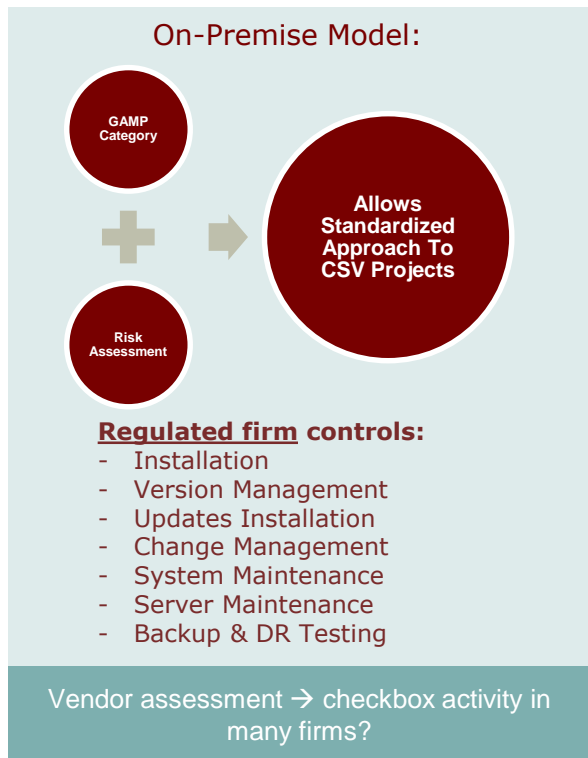
Regulatory agencies around the world are increasing their focus on compliance management for SaaS systems

- Data loss from non-validated functionality
- Visibility into vendor maintenance & security
- Access to vendor records
- Poorly defined Quality Agreements with vendors

... it is a real compliance & business risk

Validation Approach For GxP SaaS

Throw away the cookie-cutter...



Validation Approach for GxP SaaS

Vendor-specific validation does not always mean more work...

Example:

SaaS Document Management System

- “Modern” software, designed for pharma
- Detailed, easily read audit trail



- Eliminate the need for step-by-step ‘micro-detail’ test steps
- Eliminate most screenshots
- Reduce test authoring & execution cost

Audit Trail example...

Timestamp (UTC MM/DD/YYYY)	User Name	Role	Action	Field Name	Old Value	New Value	Job Instance ID	Workflow Name	Task Name	Signature	View Link	Event Description
27-Sep-2019 13:47:00 AM GMT	another1@vault.client.com	A.N. Other	14.2 GetDocumentVersion	SOP-15276								Viewed Document
27-Sep-2019 19:06:02 AM GMT	another1@vault.client.com	A.N. Other	14.2 GetDocumentVersion	SOP-15276								Viewed Document
27-Sep-2019 7:55:48 AM GMT	another1@vault.client.com	A.N. Other	14.2 GetDocumentVersion	SOP-15276								Viewed Document
28-Sep-2019 12:59:37 PM GMT	another1@vault.client.com	A.N. Other	14.2 GetDocumentVersion	SOP-15276								Viewed Document
28-Sep-2019 12:59:35 PM GMT	another1@vault.client.com	A.N. Other	14.2 TaskAvailable	SOP-15276					Second level Approval with MDCC Task			Created "Approval with MDCC" task: Second Level Approval Task
28-Sep-2019 12:59:35 PM GMT	another1@vault.client.com	A.N. Other	14.2 TaskDueDateCreate	SOP-15276					Second level Approval with MDCC Task			"Approval with MDCC" task due date set to 18-Oct-2020
28-Sep-2019 12:59:35 PM GMT	another1@vault.client.com	A.N. Other	14.2 TaskCompletion	SOP-15276	27/9/13 Approve		18-Oct-19		Approval with MDCC Task	Functional Approval		"Second Level Approval Task"
28-Sep-2019 12:59:35 PM GMT	another1@vault.client.com	A.N. Other	14.2 TaskCompletion	SOP-15276	Approve				Approval with MDCC Task	Functional Approval		"Approval with MDCC" task completes "Approval Task" with outcome: "Approval" by "Functional Approval" participant.
28-Sep-2019 12:58:24 PM GMT	another1@vault.client.com	A.N. Other	14.2 GetDocumentVersion	SOP-15276					Approval with MDCC Task	Functional Approval		Electronic signature for "Approval with MDCC" with identity: "Functional Approval" and outcome: "Approval"
27-Sep-2019 12:51:07 PM GMT	another1@vault.client.com	A.N. Other	14.2 GetDocumentVersion	SOP-15276					Approval with MDCC Task	Functional Approval		Viewed Document
27-Sep-2019 12:51:05 PM GMT	another1@vault.client.com	A.N. Other	14.2 TaskCompletion	SOP-15276	17/9/13 Approve				Approval with MDCC Task	Author Approval		"Approval with MDCC" task completes "Approval Task" with outcome: "Approval" by "Author Approval" participant.
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27-Sep-2019 9:07:09 AM GMT	another1@vault.client.com	A.N. Other	14 GetDocumentVersion	SOP-15276								Viewed Document
27-Sep-2019 9:06:09 AM GMT	another1@vault.client.com	A.N. Other	14.2 DownloadAttachment	SOP-15276								"Viewable Rendition" rendition downloaded
27-Sep-2019 9:05:57 AM GMT	another1@vault.client.com	A.N. Other	14.2 GetDocumentVersion	SOP-15276								Viewed Document

- ✓ Leverage vendor's internal QA testing & system knowledge
- ✓ Validate audit-trail first... attach audit trail as objective evidence
- ✓ Use objective-based testing:

e.g. “Create a new SOP and verify the Author cannot be an Approver” → Few navigational steps

Audit trail to minimize screenshots

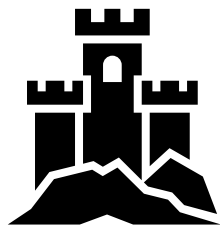
Change Management

Who can do what & when?

On-Premise:

System = fortress

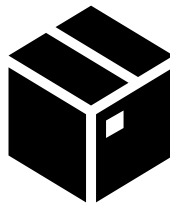
IQ = initial version control.
Validated-state preserved by
internal change management
process.



SaaS:

Without agreeing controls SaaS
change management is a 'black box'.

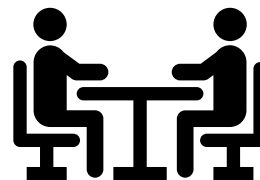
No technical controls to prevent
changes by SaaS-vendor staff.



Agree CM Process for SaaS

Define in granular detail within
Quality Agreement:

- changes that require end-user authorization
- vendor-authorized changes requiring only notification
- actions not requiring notification



SaaS Change Management

Trust but verify...

The Saturday 3am Change:

- *Vendor SysAdmin realizes the audit trail 'On' setting must be turned 'Off' while an application patch is installed.*
- *The Quality Agreement process says "Must have client QA approval"*

What will the SysAdmin do?

How would you know?

- Some vendors → no client access to system config
- Most vendors → allow config snapshot at any time

➤ Comparing IQ config snapshot to current state = compliance verification

➤ Problem:

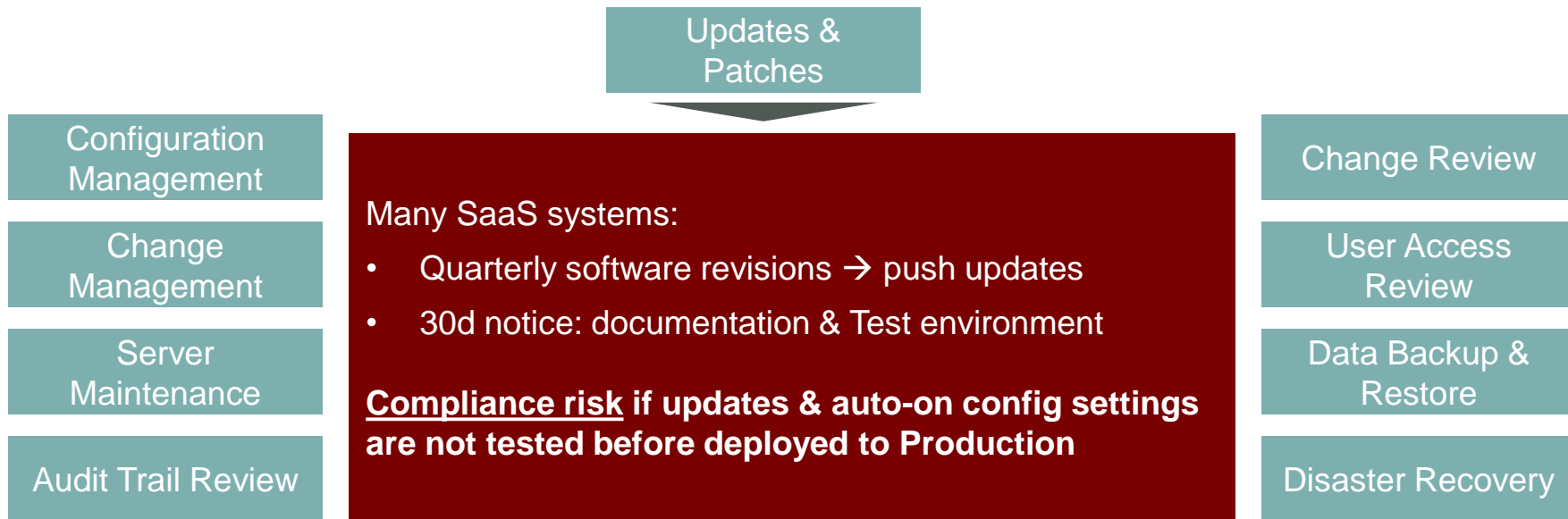
Config snapshots → usually complex xml files...
not very human-readable

Some values are dynamic → false-hits...
needs filtering mechanism

Use of platform-specific config comparison tools
e.g. NNIT Veve Vault comparison

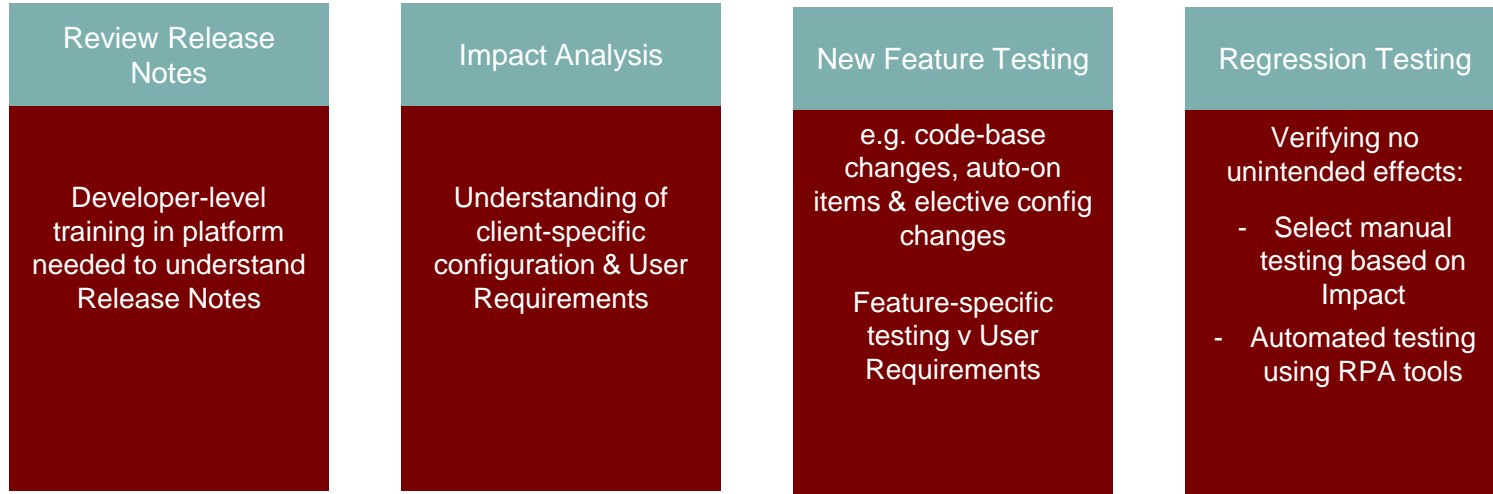
Operations & Maintenance

Everything you do in on-premise... who is doing it in SaaS?



Operations & Maintenance

Release Management: Making regression testing cost & time efficient



New Business Risks

Every process change brings anticipated benefits plus new risks



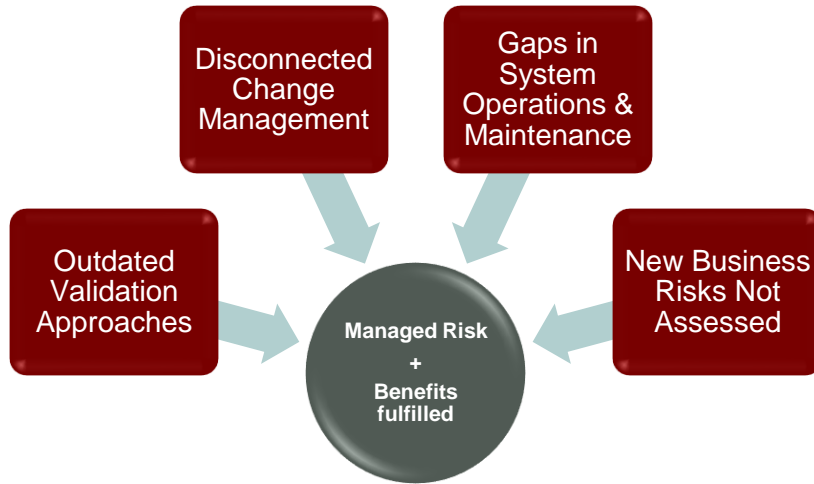
You no longer control everything about your own data...

- How long would it take the vendor to do a worst-case system restore?
- How much data could you lose?
- What would happen if the vendor became insolvent?
 - How would reclaim possession of your data?
 - Could you read your data / use the software?

All of these issues are readily managed if planned for...

Deploying GxP Cloud Solutions

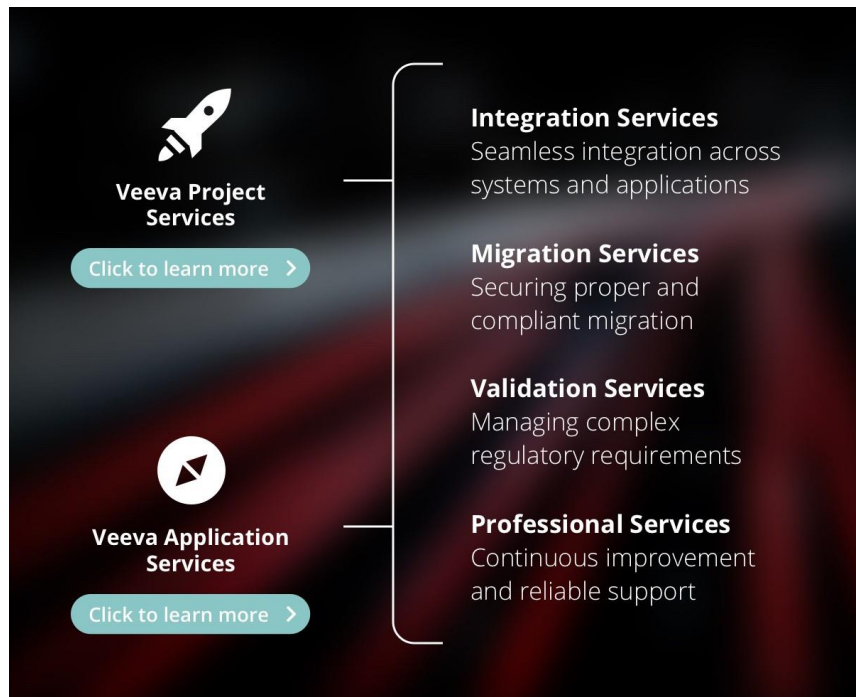
Maximize the opportunity... by mitigating the risks



- Define the client-vendor relation in detail in the Quality Agreement
- Think! about the process for each vendor... Avoid *"use the same QAG we used for that other vendor"*
- Take advantage of new tools & methods to reduce the cost & time needed to validate
- Use new processes & tools for:
 - Change detection
 - Release Management & Regression Testing

NNIT Veeva Powerhouse Services

Bringing it all together...



- Development & validation expertise
- Focused on main GxP Vaults: RIM; Clinical; and Quality
- Experienced in the most complex data migrations (Valiance Inc.)
- 30+ certified Veeva Vault Admins.. and counting
- Global execution capabilities, with local US offices in pharma hub cities



Thank You

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