



# Computerized System Implementation Insights

Moshe Radovitch

[mosherad@tera-zon.com](mailto:mosherad@tera-zon.com)

[www.tera-zon.com](http://www.tera-zon.com)

---

30 July 2017

System acquisition is essential step

Sure.. obviously

So how come the purchased systems do not fulfill the expectations (sometimes)

(Computerized System)

Mainly referred to Operation Technologies (OT) and includes Labs, Prod & Calibration Computer systems.

# Data governance

The Acquisition process is part of the Realization (implementation). It has Impact for the entire System Lifecycle and the capability to governance the collected quality data

## Structure & Objective elements

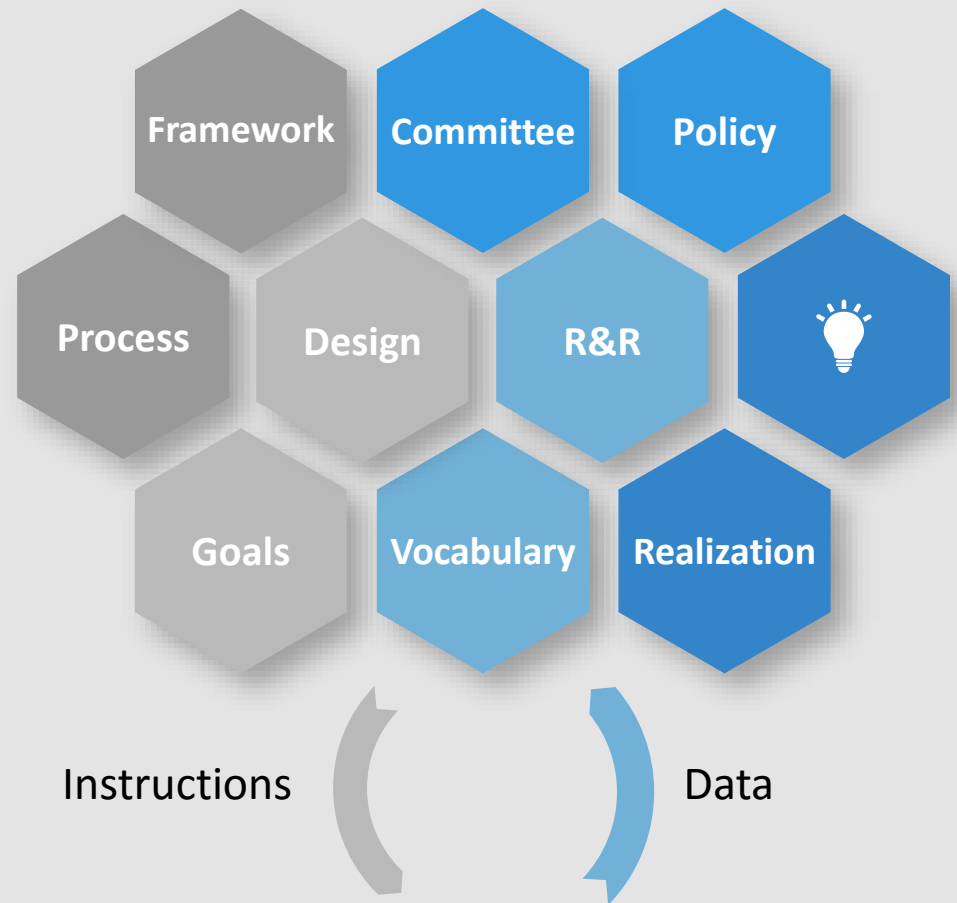
At the best

### Preventive Oversight

- Quality
- Business

Influenced by

Senior-level Sponsorship  
Cultural barriers  
QMS  
Organization  
Technology



## System Life Cycle



# Acquisition

Initiation – Days to Years

Design

URS

Offers / proposal

Review

Negotiation

Months to Years

The steps prior actual purchasing  
(Pre Purchasing) is in the focus  
The steps can be mixed and  
repeated.

Purchase – Hours to Weeks

# Acquisition

Initiation

Design

URS

Offers / proposal

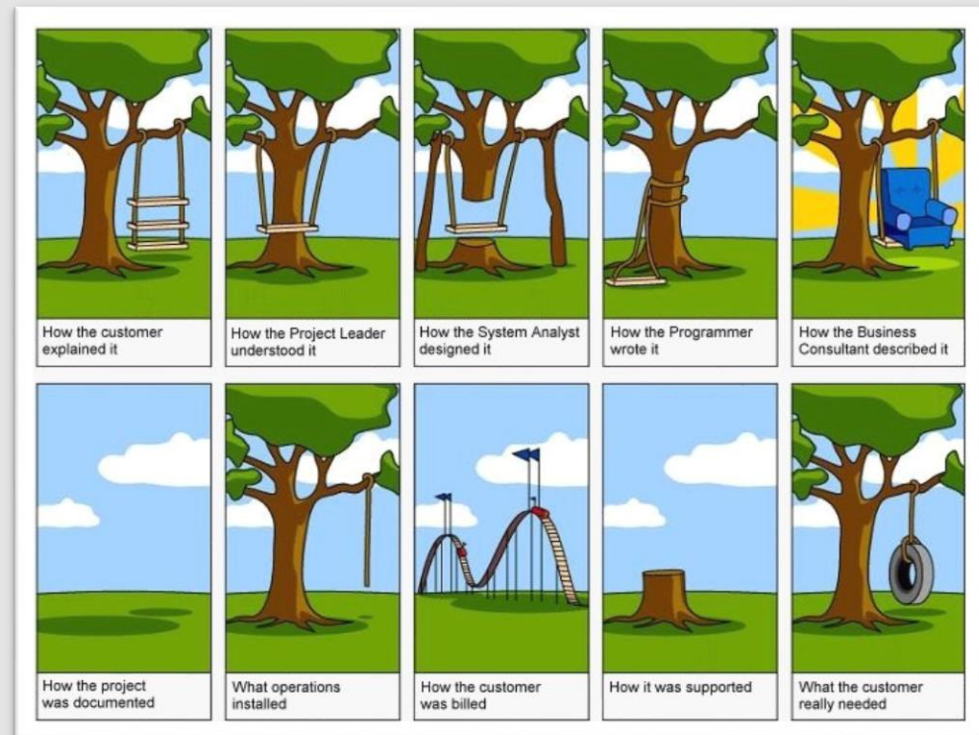
Review

Negotiation

Purchase

Ensure that technical people nominated and dedicated to support the Pre Purchasing phase.

Avoid the results below



# The Case

## Torque Meter

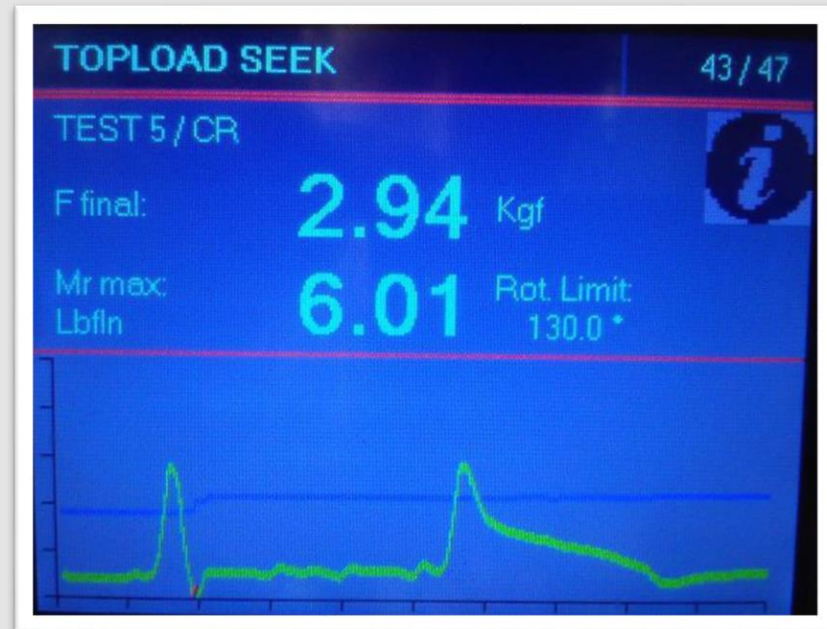
Testing device that measures and record the force to rotate the cap of a medicine bottle

PC and application are required to log the data.

The case is relevant to several OT systems in labs, production & calibration.



Sure Torque – Bench-top torque tester



# The Case

The proposal include

- The meter is capable of managing unique users
- The meter is connected to a PC to log the data
- The PC & application installed by the client
- Backup is set by the client
- 3 Level of permissions

In the price proposal

**Cable Torqo To Pc Via RS-232 Port – 65\$**

Why this cable is required??

# The Case

Asking the salesperson

*Why we need the cable?*

*Salesperson: To collect the data from the meter to the PC*

Thinking to myself

*2017, who is collecting data with RS232 data cable.*

In other words

*Why play music using vinyl disc if we use Flash Drive*

Ok.. Deep dive to the architecture is required

The bread crumbs in the Pre Purchasing phase can help to understand the full story (architecture) of the computer system. The hardware configuration can reveal software issues, and vice versa.

Technical staff should not stop inquiry until the system is fully understood.

# The Case - Findings

The meter is connected to the PC with a RS232 cable.  
SQL is installed on the PC.

Cannot connect the meter to the organizational Database at least not directly

The meter is connected to a PC to collect the data

The PC & application installed by the client

The cable is not secured, operator can rerun / retest / Avoid results

1. The quality and technical members need to work together to understand the actual impact of each technology on quality requirements.
2. Local database complies with Data Integrity requirements, but Data Lifecycle and Data Governance will benefit from a central database

Unique users feature is not relevant

Each user needs to login to the device with his set of configuration.

And..We don't want different set of configuration

# The Case - Findings

Backup the meter a Flash Drive.

No full Audit Trail

Basically, all manufacturers provide the same architecture

The Pharma is not first priority to a system provider.

The System security is not sufficient

The system purchasing & implementation was done with the provided configuration and manual controls

# Audit Trail and Metadata, a few words

Audit Trail is important, but metadata can be found in other places.

User management, Firewalls, in & Out of a database, reports, Cloud Computing, Network switches.

Occasionally System provider doesn't know where is all the metadata

Central solutions may ease the handling of metadata & data

In some cases, Data and Metadata can span through distant sites and computers' cloud. Data Governance team should understand that such architectures exist and refer to it.

# Cyber attacks and Security, a few word too

“WannaCry” ransomware

Files encryption by the crypto-worm

Step 1 Distribution

Step 2 Files encryption

Step 3 Ransom message.

Backup on Regular basis



# Cyber attacks and Security, a few word too

The WannaCry distribution model affected computers but not PLC, The PLC variety is wide, and the worm was not planed for PLCs

Computers security is weak.

System providers does not guarantee operation with installed Anti-Virus.

The Pharma industry should demand security changes, including Anti-Virus. However, such changes are not immediate.

PLC security is weak too.

Hundreds to Thousands PLCs without a password.

Put password to the central PLCs

## OT attacks evolve.

The same exploiting tools fits power plant and Pharma

# Conclusions

Organization parties need to understand the basis of IT

Pre Purchasing - Review thoroughly what is provided.  
URS, BOD, Price Proposal, Provider documentation, Mails,  
Etc.

Be familiar with the manufacturers and contractors.

Consider nominate Enterprise Architect

# Strategic view

IT participation from initiation step

Ask the system provider to supply Automatic backup solution and DR plan

Central users' management (Active Directory)

We want raw data, not imaged data (PDF)

Cyber attacks - Central, Local, contractors, and providers, be prepared

Thank You  
For Your Attention