Gsap by Novolog

Gsap
Integrative Impact
by Novolog

The Right Way to Process Validation

MDI Conference - Design Practices Track

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Novolog
Delivering Health

Accelerating Healthcare Companies

Gsap aspires to enhance development and maturation of healthcare companies and to empower them to achieve significant therapeutic solutions for patients worldwide by providing regulatory, quality, engineering and clinical solutions

- Gsap was Founded in 2009, since 2022 part of Novolog group
- Novolog is listed on the Tel-Aviv Stock Exchange since 2017 (TA125)
- 450 active project per year
- Up to 70 employees
- Strong, stable, debt-free financial balance
- Supporting variety of clinical trials from cell therapy to digital health

Agenda

01. Introduction- What is PV?

02. Why?

03. When?

04. How? Process Validation Life Cycle

05. Case Studies

01.

Introduction

What is PV

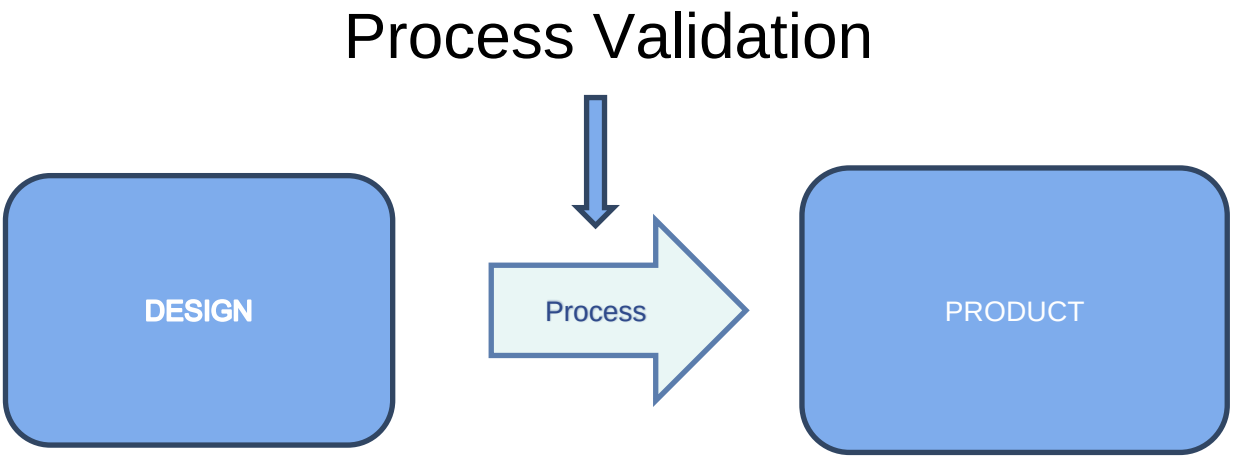
Definition

Process Validation according to the FDA:

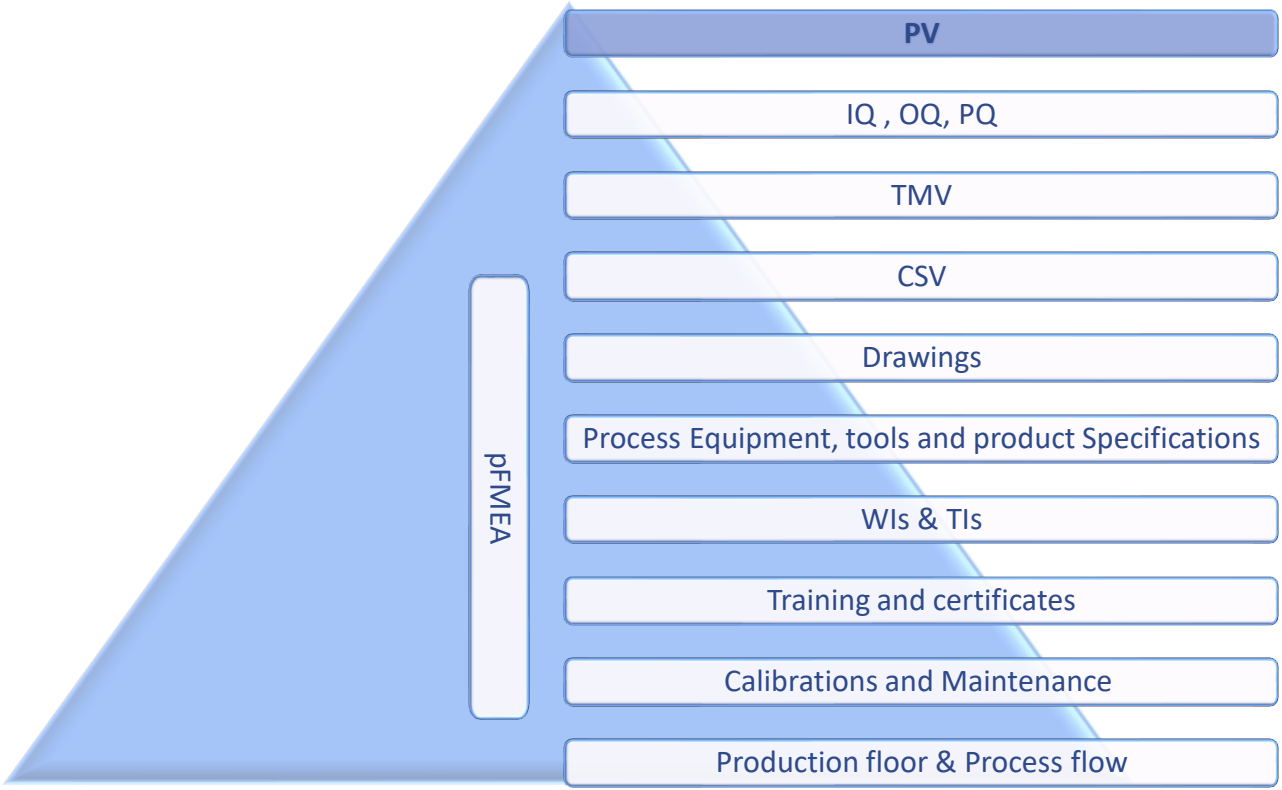
"establishing by objective evidence that a process consistently produces a result or product meeting its predetermined requirements."

קביעה ע"י ראיות אובייקטיביות שתהליך היצור מספק בעקביות תוצאה או מוצר העומדים בדרישות שנקבעו לו מראש.

Introduction



End-to-End Process Validation



02.

Why

Why should I preform PV

Regulations and Guidance

Regulation and Guidance

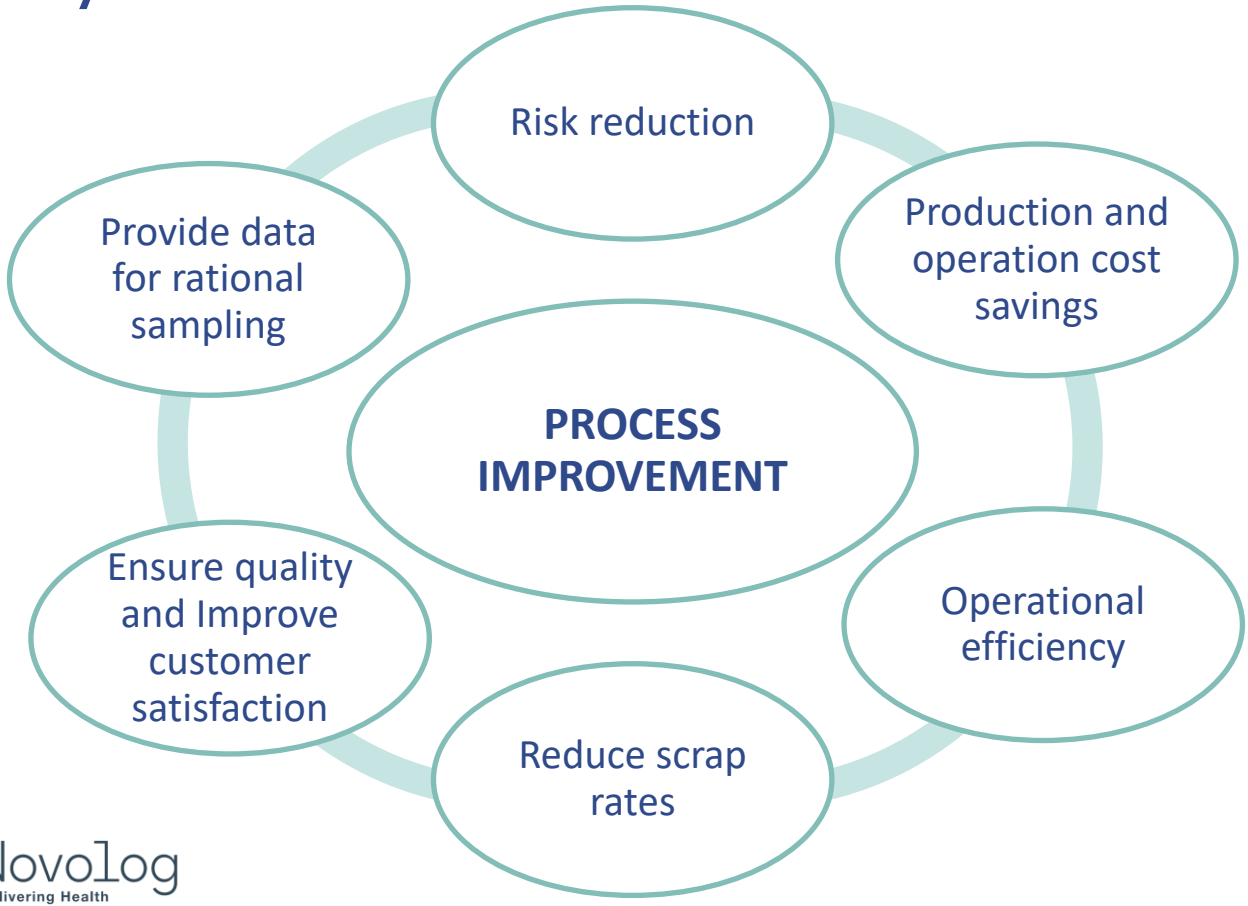
FDA CFR Part 820.75: Process validation

(a) “Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures.”

Process Validation by ISO 13485

“The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement.”

Why Preform Process Validation?

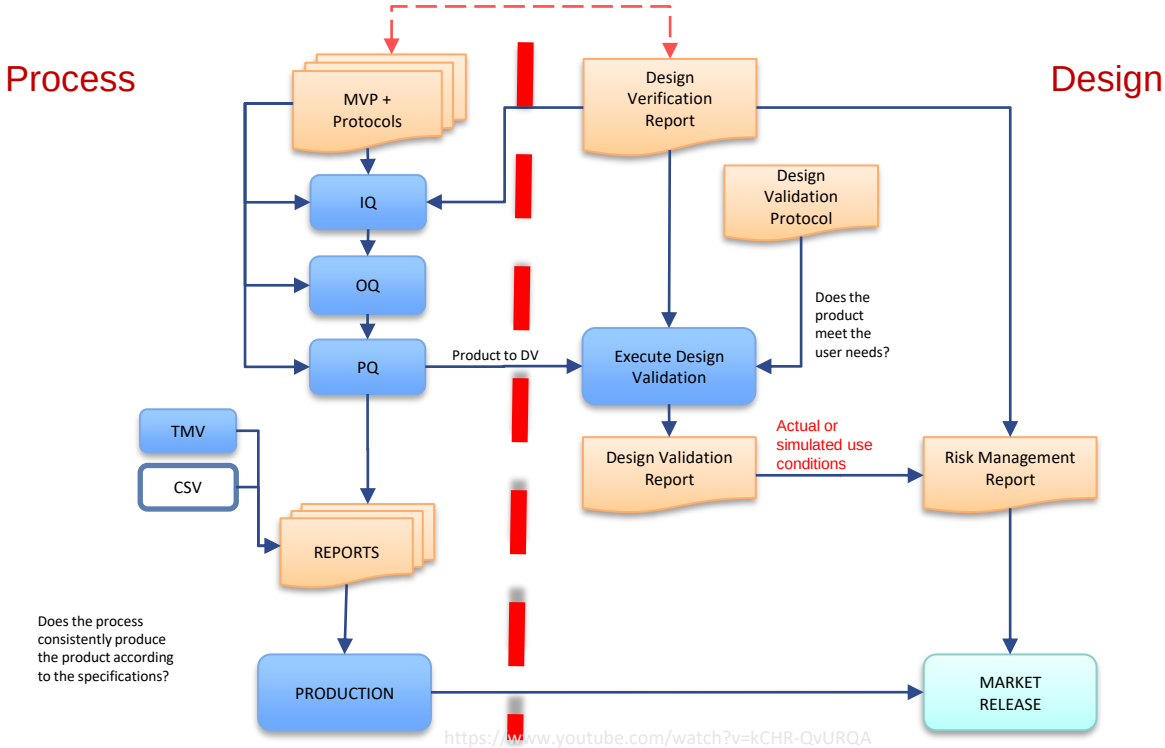


03.

When

When Should I preform PV

Process Validation & Design Control

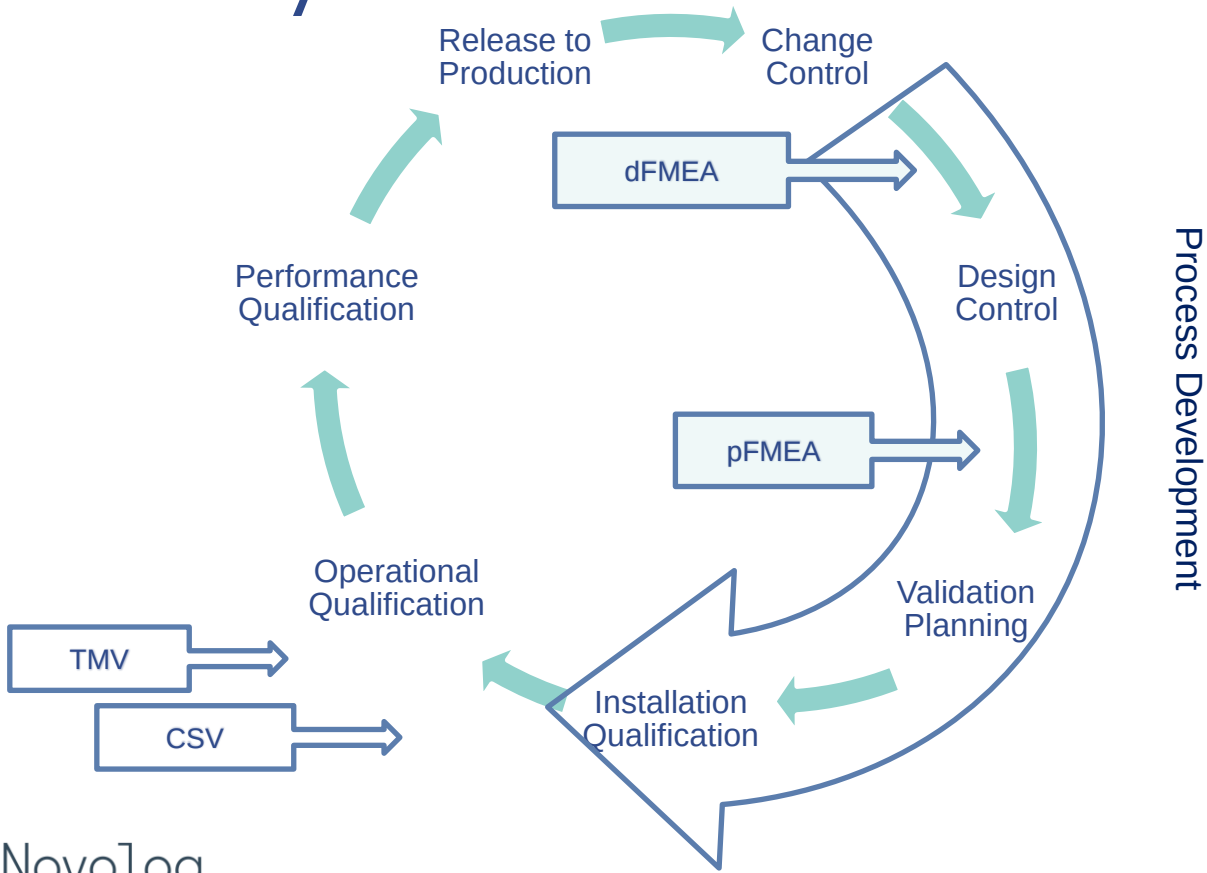


04.

How

How is PV done? Or PV life cycle

PV Life Cycle



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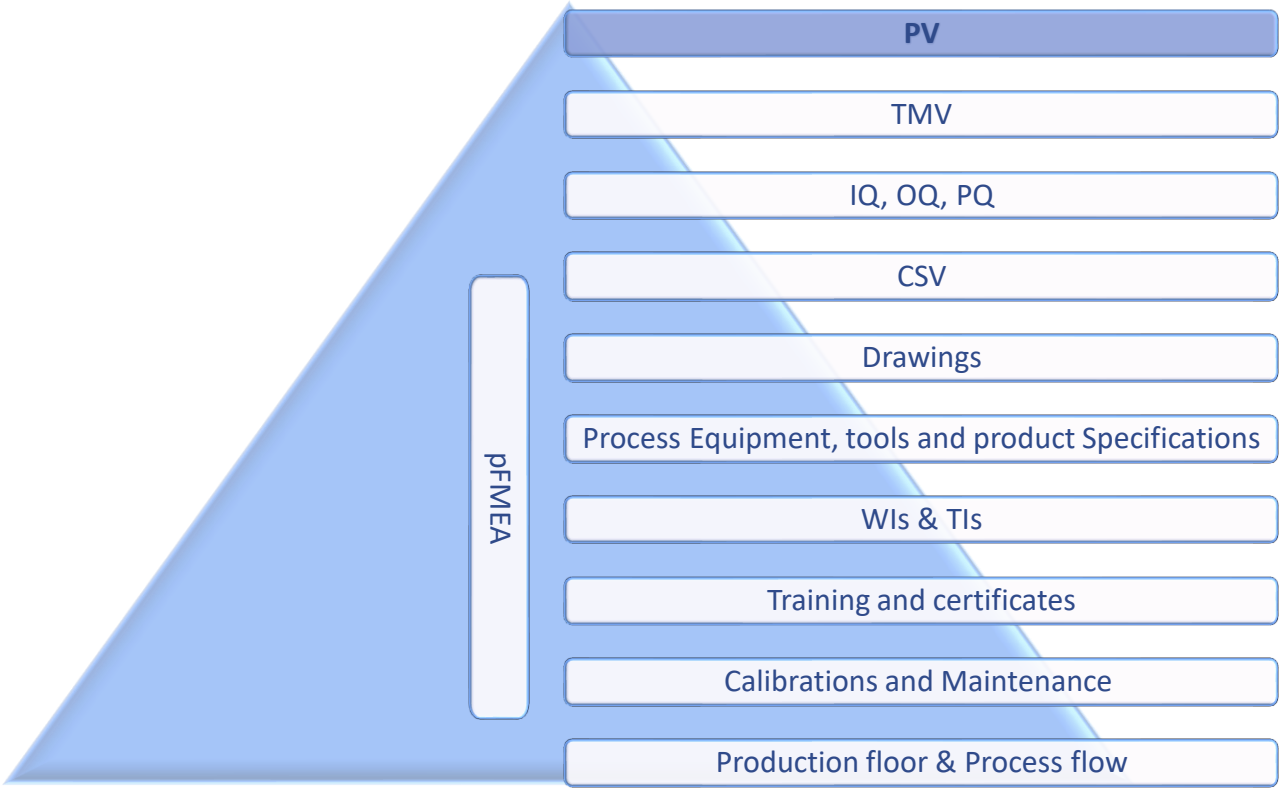
End-to-End Process Validation



05.

Case Studies

Real life examples

Case Study 1

Process Validation project at a MD company that uses sub-contractor for all of its manufacturing.

The Challenge:

Measurement Systems (Jigs and tools) that were used for measuring in the manufacturing process were not validated

GSAP Solution:

Implementation of TMV (Test Method Validation) to validate the test methods used as part of the process

Test Method was successfully validated!

Case Study 2

The management of a MD used for implant, decided to validate and to re-validate part of the the production line inside the facility

The Challenge:

How and what to sample?

GSAP Solution:

Review and update relevant procedures and documents

Creating qualification protocols

Coming up with a sampling plan, as part of PV, that:

1. Makes sense
2. Take into account the adequate reliability and confidence level
3. Risk based

Ended up with a successful Validation!

Case Study 3

A MD company that developed a new product for mass production, asked for our support in PV

The Challenge:

The existing PV was not supported by a robust pFMEA

GSAP Solution:

Go back to basics and preform a more thorough pFMEA

Writing Validation Plan that mitigates all the new risks

PV was conducted successfully according to the risks and regulatory demands and according to the PV life cycle!

Thank you!

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