

ASSEMBLY OF SYRINGES AND ADMINISTRATION DEVICES

Agenda

1. Introduction
2. Device Selection
3. Production Platform strategy
4. Assembly and Labelling

INTRODUCTION

Introduction

Moeller & Devicon, a Bosch Packaging Technology company

Facts & Figures

- ▶ Established in **1962**
- ▶ Acquired by **Bosch** 2003 & 2007
- ▶ Headquarters: **Sandved**, Denmark
- ▶ Quality: Bosch Guidelines, GMP /**GAMP5**, **ISO9001**, ISO14001, OHSAS18001
- ▶ **6000 m2 production** and 2400 m2 office facilities



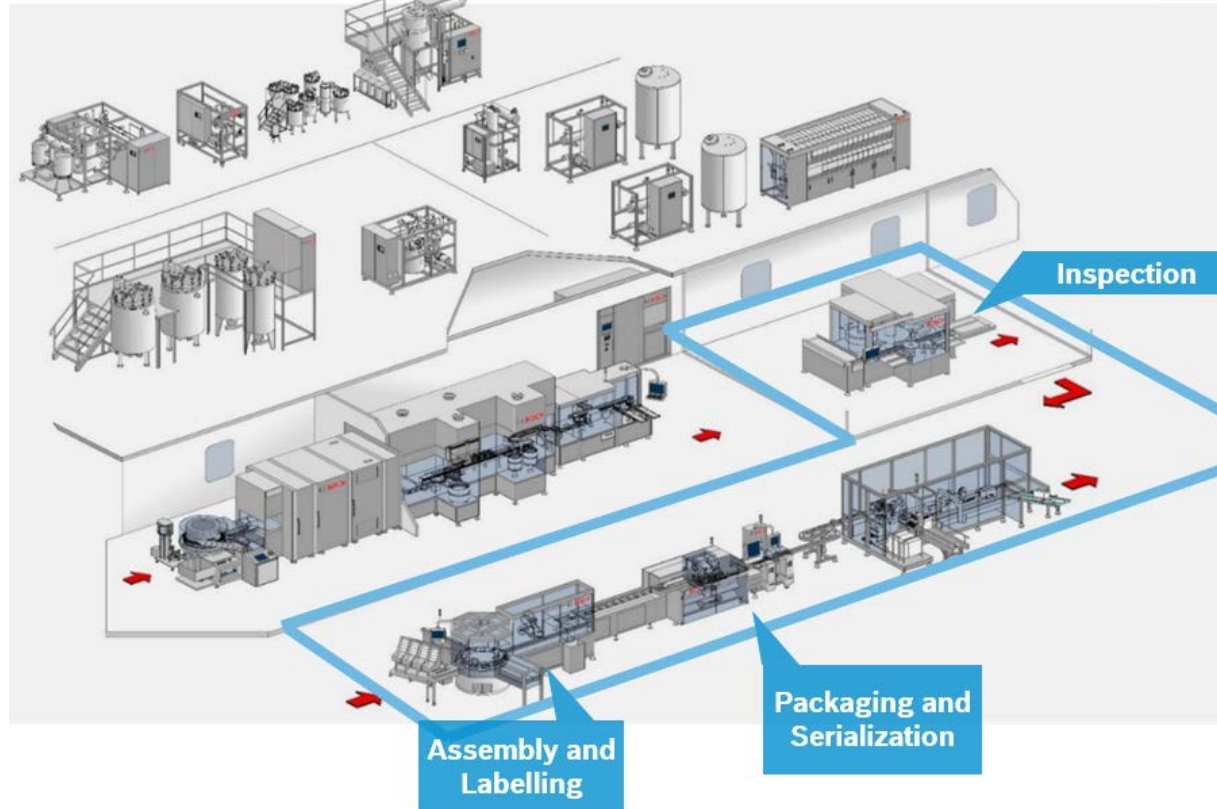
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Experience

- ▶ Around **300 references for Pharma & MedTech** since 1995
- ▶ Experienced in working with high-end customers **around the globe**
- ▶ More than **45 assembly machines for Pens and Auto Injectors** over last 5 years
- ▶ More than **90 projects** with a **single** well-known Pharma **manufacturer**

Introduction

Moeller & Devicon, a Bosch Packaging Technology company



- ▶ Our portfolio covers all processes outside of the cleanroom
- ▶ Smart and compact lines: Visual inspection, CCIT, assembly, labelling, cartoning to serialization and aggregation

DEVICE SELECTION

Device selection

Device landscape

- ▶ Current landscape seen from machine supplier
- ▶ Trends seen from machine supplier



Device selection

Initial requirements

- ▶ Intended use
- ▶ Patient population
- ▶ Feedback to user during use
- ▶ Strength required for use
- ▶ Injection sites on body
- ▶ Frequency of injections
- ▶ Device use
- ▶ Dose range
- ▶ Drug Viscosity
- ▶ Injection time
- ▶ Adjustable dose
- ▶ Capacity required, now and future

Device selection

Parameters affecting your choice

Commercial device

- ▶ Off-the-shelf technology
- ▶ Fixed design
- ▶ No development
- ▶ Proven and tested

- ▶ Business continuity plan required
- ▶ No differentiation
- ▶ No ownership of rights

▶ Customized device

- ▶ Open Off-the –shelf technology
- ▶ Adaptable design
- ▶ Limited development
- ▶ Might be proven and tested

- ▶ Business continuity plan required
- ▶ limited differentiation
- ▶ potential ownership of rights

▶ Own device

- ▶ Novel technology
- ▶ Full control of design
- ▶ Full ownership of rights

- ▶ Long development time
- ▶ High Risk and cost
- ▶ Full ownership if rights
- ▶ Require full test and verification

Device selection

Partner selection

- ▶ Technical and commercial assessment of device partner
- ▶ Stage of device development
- ▶ Documentation available
- ▶ Flexibility for customization
- ▶ Functionality and performance testing
- ▶ Development timeline & cost for customization
- ▶ Fall-back plan

PRODUCTION PLATFORM STRATEGY

Production strategy

Initial considerations

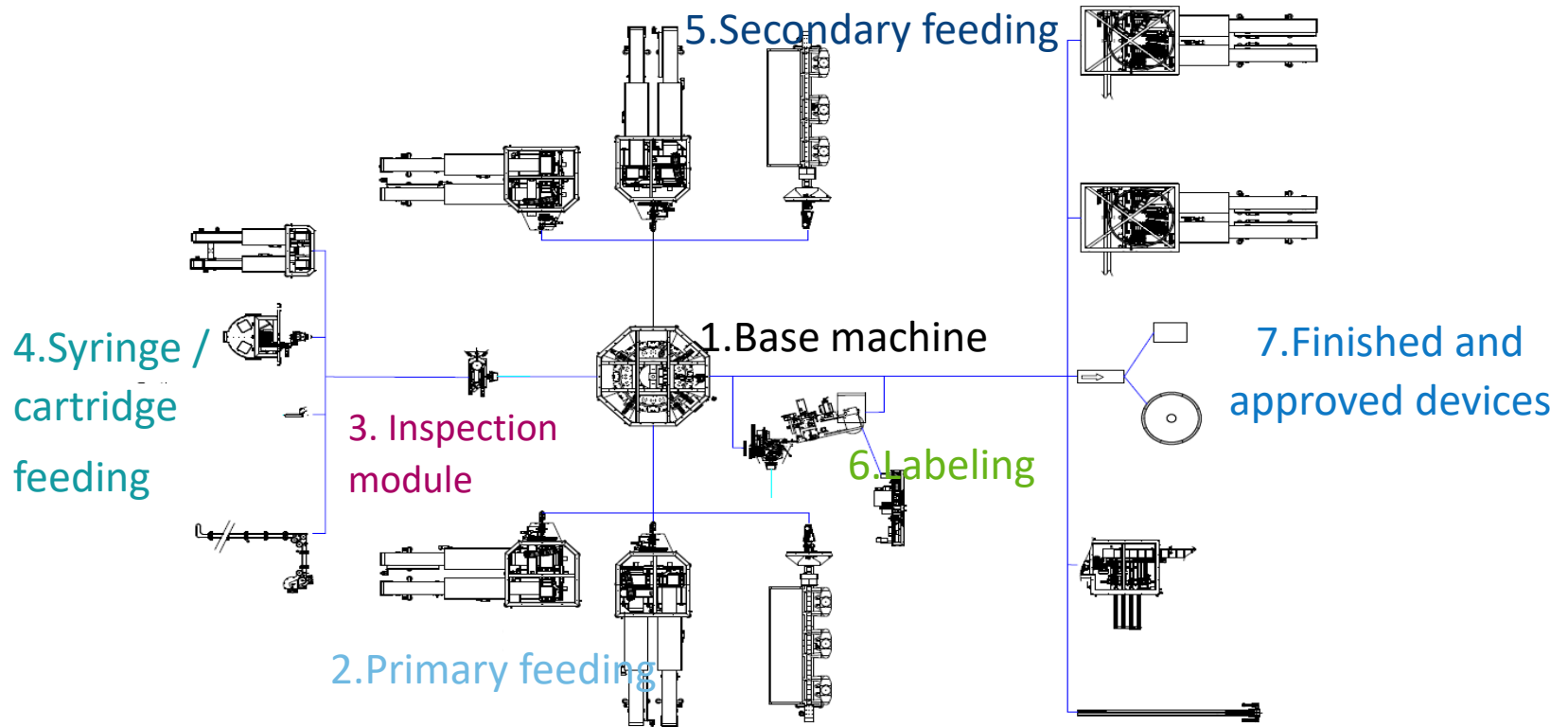
Low demand

High demand



Platform strategy

Platform Configurations



ASSEMBLY AND LABELLING

Assembly & Labelling

Key information affecting solution

Assembly

- ▶ Assembly guidelines
 - ▶ Customization of device
 - ▶ Component tolerances
 - ▶ Assembly forces
 - ▶ Accept criteria
- ▶ Customer specific checks and verifications
- ▶ Data collection strategy
 - ▶ Device assembly data
 - ▶ Productivity data

Labelling

- ▶ Device shape
- ▶ Label design and print area
- ▶ Variable data specification
- ▶ Label positioning
- ▶ Label customization

Assembly & Labelling

Auto-injector, final assembly steps

- ▶ Device component infeed (lower sub-assembly & top sub-assembly)
- ▶ Device component pre-inspection
- ▶ Syringes infeed
- ▶ Syringes pre-inspection:
 - ▶ Plunger present & position
 - ▶ RNS present & angularity
 - ▶ Flange inspection
 - ▶ Liquid present.
- ▶ Syringes seating
- ▶ Seating of top sub-assembly
- ▶ Assembly verification
- ▶ Labelling incl print of variable data

Assembly & Labelling

Pen device, final assembly steps

- ▶ Device component infeed (Dosing device, Cartridge holder & Cap)
- ▶ Device component pre-inspection
- ▶ Cartridge infeed
- ▶ Cartridge pre-inspection:
 - ▶ Plunger present & position
 - ▶ Cap color or data matrix verification
 - ▶ Cartridge rim inspection
 - ▶ Liquid present.
- ▶ Cartridge seating in Cartridge holder
- ▶ Check of rod position and plunger position
- ▶ Seating of dosing unit onto
- ▶ Priming
- ▶ Assembly verification
- ▶ Labelling incl print of variable data

Assembly & Labelling

Safety device, final assembly steps

- ▶ Device component infeed (Piston rod, Safety unit & Finger flange)
- ▶ Device component pre-inspection
- ▶ Seating of finger flange on safety unit
- ▶ Syringes infeed
- ▶ Syringes pre-inspection:
 - ▶ Plunger present & position
 - ▶ RNS present & angularity
 - ▶ Flange inspection
 - ▶ Liquid present.
- ▶ Piston rod insertion
- ▶ Syringes seating in safety unit
- ▶ Assembly verification
- ▶ Labelling incl print of variable data on to the safety device (can be labelled on syringe prior to assembly)

For further information please contact us at:

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BOSCH

Parkhaus

THANK YOU