

# BFS Machine Maintenance

Presented by Christoph Bohn

Director Rommelag Pharma Service  
Senior Technical Manager Rommelag CMO

## 三合一无菌灌装技术论坛 BFS TECHNIQUE FORUM

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主办单位  
Hosts

中国医药质量管理协会  
China Quality Association for  
Pharmaceuticals

国际吹灌封技术协会  
The Pharmaceutical Blow-Fill-Seal International  
Operators Association (BFS IOA)

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## **Maintenance in the GMP Guidelines**

《药品生产质量管理规范（**2010**年修订）》

**Good Manufacturing Practice (2010 revision)**

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# Chinese GMP - Responsibility

Article 22: The head of the Production Department

(2) The **head of production department** generally has the following responsibilities:

- iv. **to ensure the maintenance of premises and equipment to keep them in good conditions;**

Article 23: The head of quality management

(2) Main responsibilities:

- iiv) To check the maintenance of premises and equipment for the purpose of maintaining a sound operating state;
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# Chinese GMP – Premises and Facility

## Section 1 Principle

Article 38: The location, design, lay-out, construction, adaption and **maintenance of premises should suit the drug production requirements**, and should minimize the risk of contamination, cross-contamination, mixups and **errors**, as well as **permit effective** cleaning, operation and **maintenance**.

Design  
Lay-out  
Construction

Training  
Technical and  
GMP

Preventive  
Maintenance

# Chinese GMP – Premises and Facility

## Section 1 Principle

Article 41: **Premises should be carefully maintained, ensuring that repair and maintenance operations do not present any hazard to the quality of products.**

They should be cleaned and, where applicable, disinfected according to detailed written procedures.

Design  
Lay-out  
Construction

Training  
Technical and  
GMP

Preventive  
Maintenance

# Chinese GMP - Equipment

## Section 1 Principle

Article 71: The design, selection, installation, adaption and **maintenance of equipment** should be suitable for its intended use, minimize the risk of contamination, cross-contamination, mixups or errors, and **facilitate** operation, cleaning, **maintenance**, as well as disinfection or sterilization if necessary.

Design  
Lay-out  
Construction

Training  
Technical and  
GMP

Preventive  
Maintenance

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# Chinese GMP - Equipment

## Section 1 Principle

Article 72: **Procedures** for the use, cleaning, **maintenance and repair of the equipment** should be established, and their **operation records** should be retained.



SOP

Record

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# BFS MACHINE DESIGN DARK-WHITE INSTALLATION

**Secondary  
Packaging  
Not classified**

**Optical clean  
etc.**

**Technical Area  
(Dark Side)  
Not classified**

**Surrounding Area  
(Clean Room – White Side)**

**Room Class C**

**Class A/B Gowning**

**“at Rest” viable and non viables**

**“in operation” for non viables**

**Effective Air  
shower grade A**





# Chinese GMP - Equipment

## Section 3 Maintenance and Repair

Article 79: **Repair and maintenance operations should not present any hazard to product quality.**

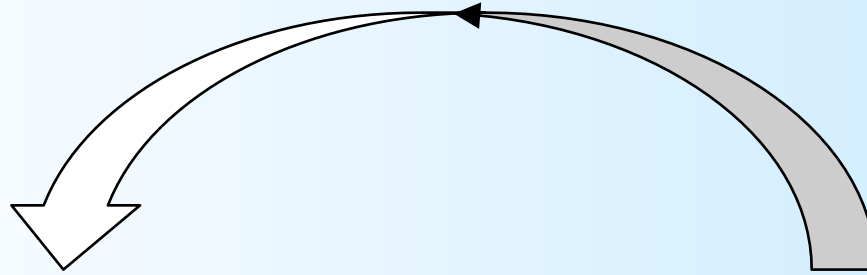
Article 80: **Preventive maintenance plans and procedures should be established, and the maintenance and repair activities should be recorded.**

SOP

Training  
Technical and  
GMP

Record

# GMP- Principle



Risk Analysis  
Maintenance Plan = SOP

Records

Report, Analysis,  
Action Plan

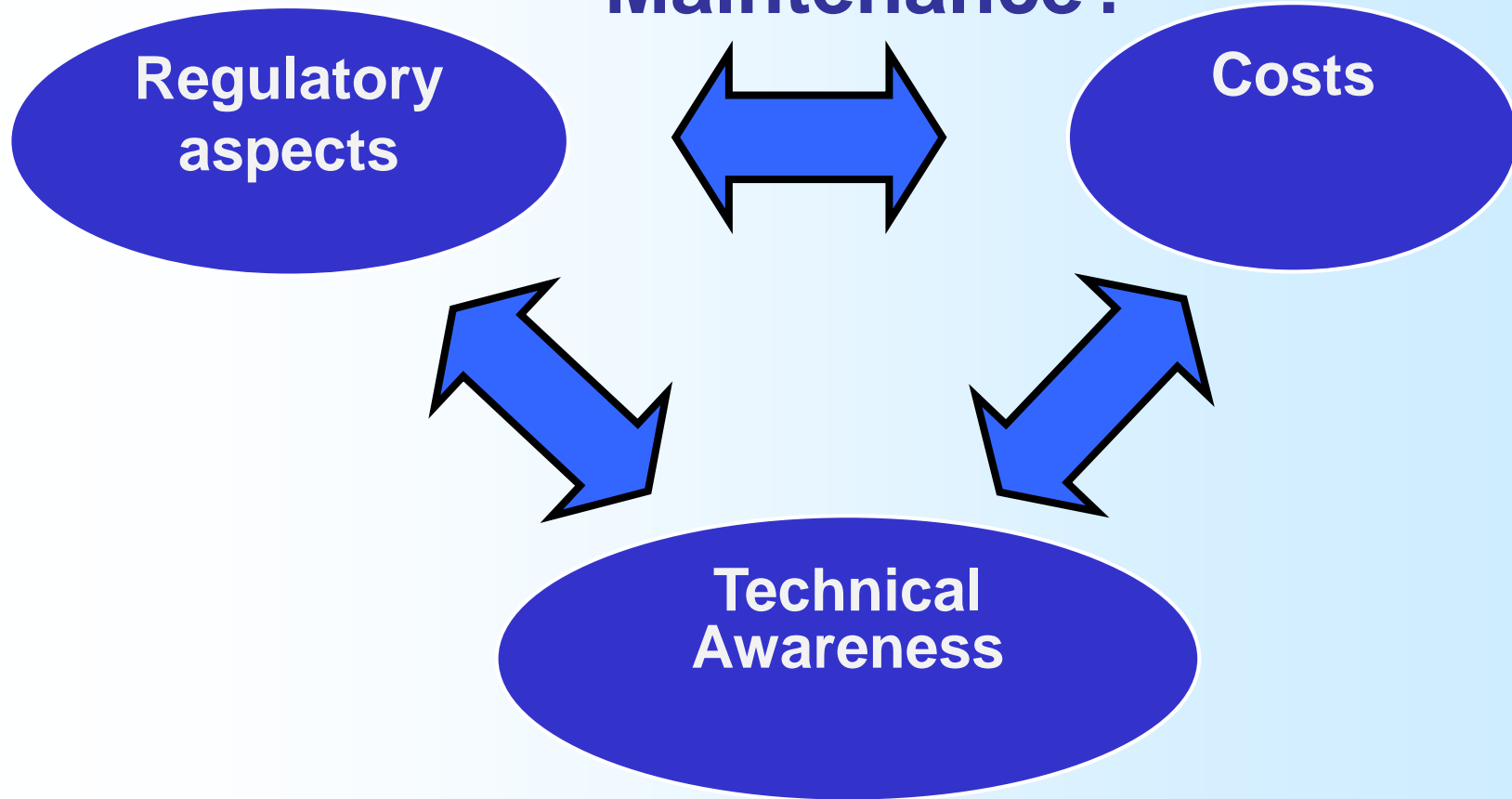


THINK DEFINE

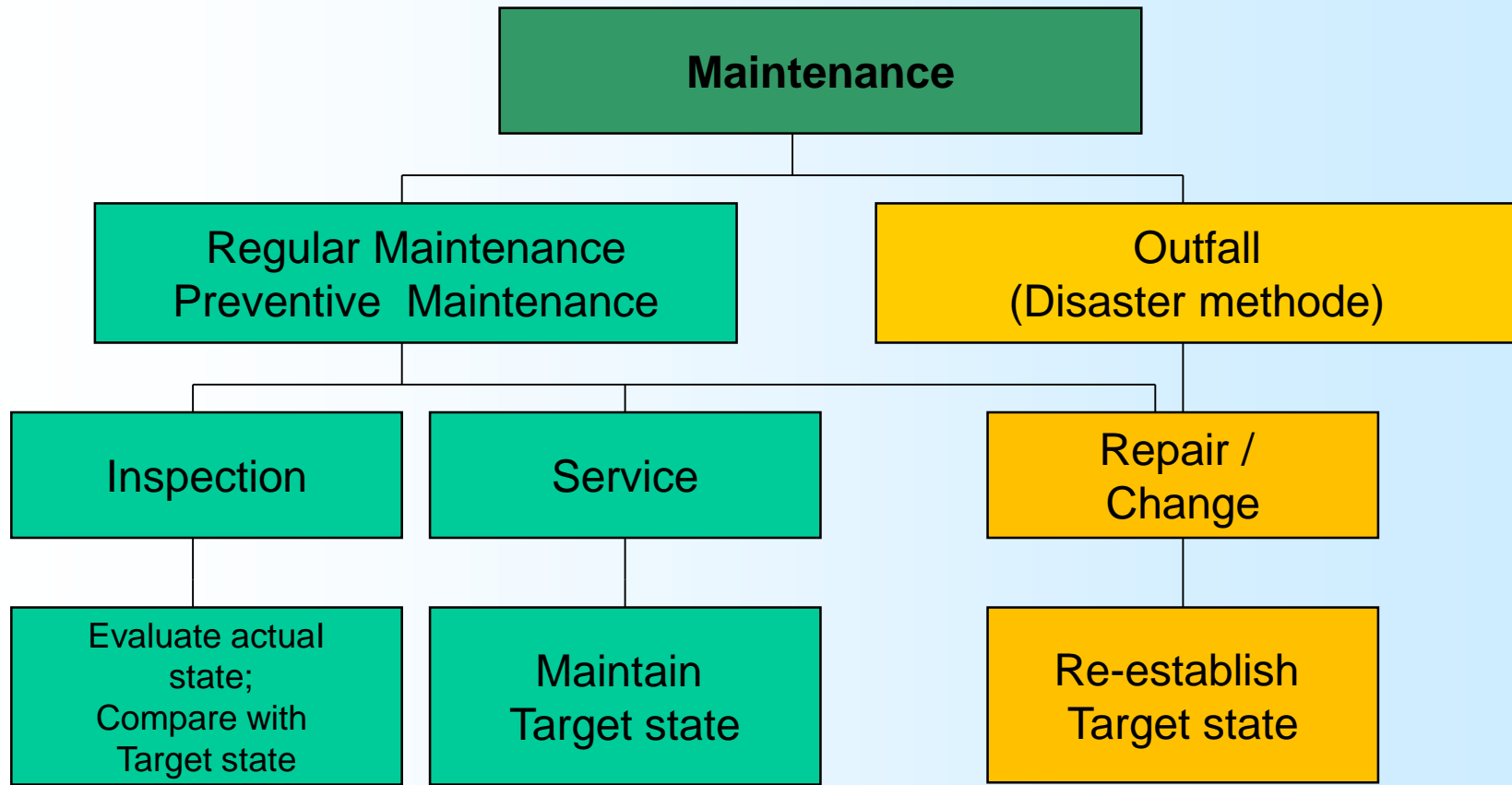
ACT

REPORT

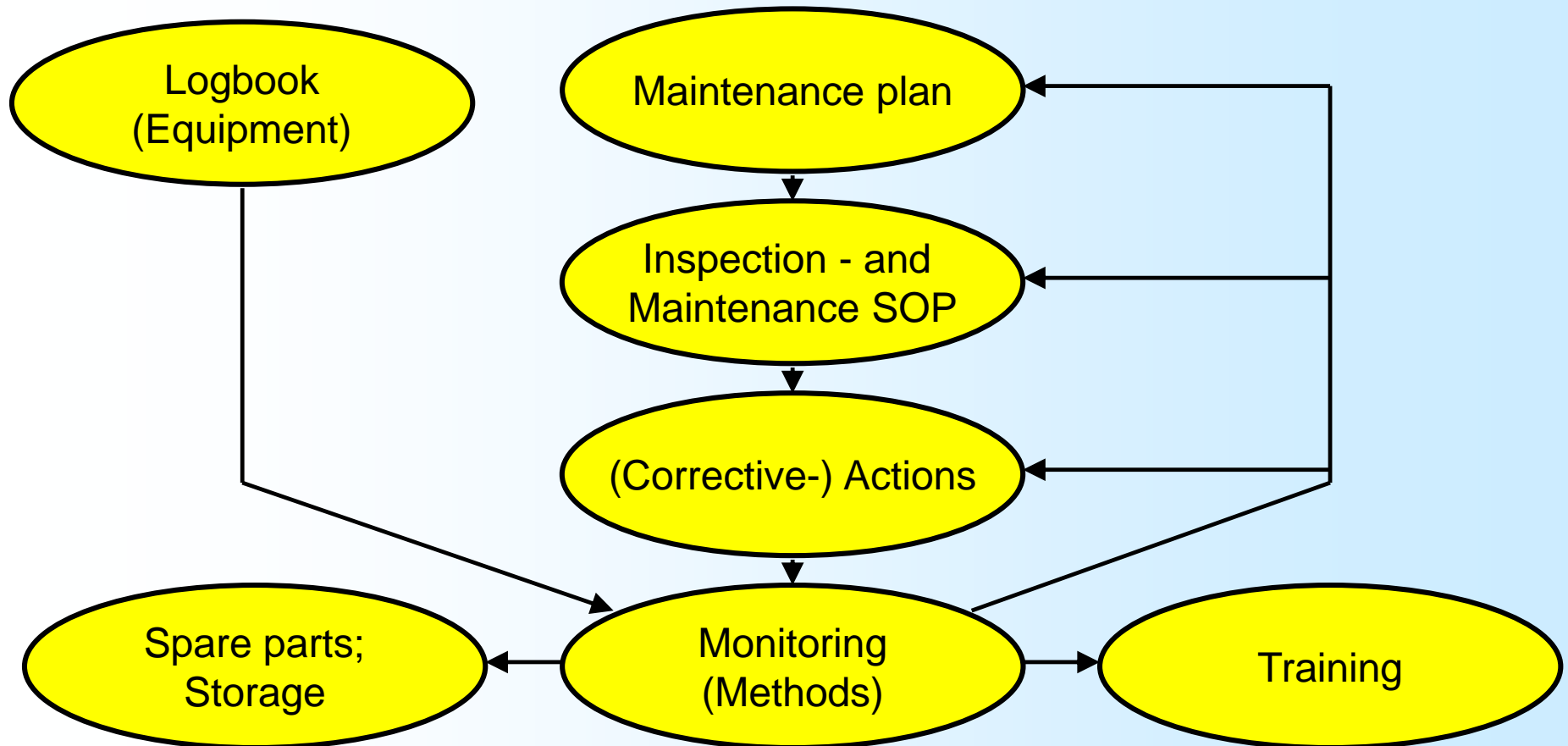
# What is an effective and GMP conform Maintenance?



# Maintenance Concept



# Organization of Maintenance



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# Organization of Maintenance

- 1. Maintenance Concept**
- 2. Inspection- and Maintenance SOP**
- 3. (Corrective-) Actions**
- 4. Monitoring / Trending / Analysis**

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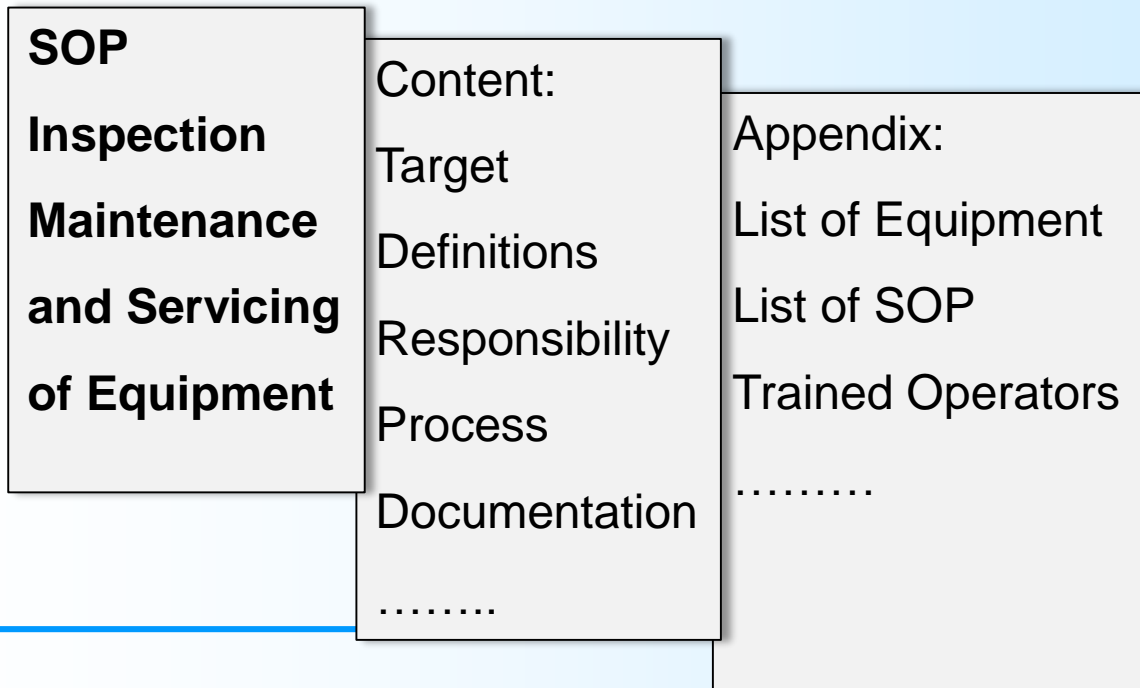
# Organization of Maintenance

## 1. Maintenance Concept

- Time schedule (over one year or longer)
- Responsibility for inspection, maintenance, reporting, approval,
- Knowledge
- Training, Training, Training
- Documentation of maintenance activities
- Analysis, reporting => Quality review

# Organization of Maintenance

## 1. Maintenance Concept





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# Organization of Maintenance

## 2. Inspection- and Maintenance SOP

- How to do (when, what, with )
- Responsibility for doing (who)
- Documentation
- Reporting and Analysis
- Approval

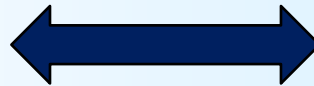
# For Blow-Fill-Seal:

## Inspection and Maintenance SOP

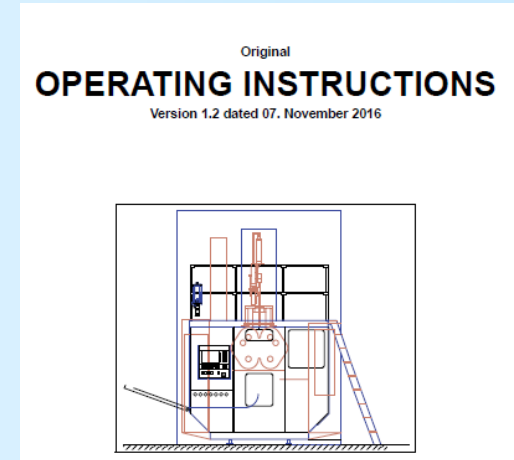
Protocol => Record



**Equipment**



## Documentation

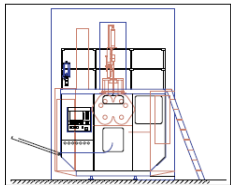


## For Blow-Fill-Seal:

➤ How to do (**when, what, with** )



Original  
**OPERATING INSTRUCTIONS**  
Version 1.2 dated 07. November 2016



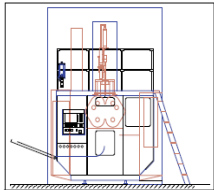
Interval	Location	Measure	Info/Aids
Weekly	Mould chain	Entire mould chain: Relubricate chain elements using lubricant nipples	☞ Lubricant nipple Pos. 14 *Appendix II-35  Multi-purpose grease LE 3752
	Mould chain	Relubricate cover on contact side to cams for "Mould opening"	☞ Cover Pos. 70 *Appendix II-35  Grease high-temperature Molub-Alloy 9830
	Mould tool	Relubricate centring pins	Grease high-temperature Molub-Alloy 9830

## For Blow-Fill-Seal:

➤ How to do (**when, what, with** )



Original  
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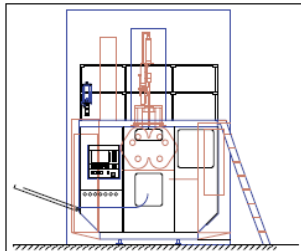
Interval	Location	Measure	Info/Aids
3,500 h (6 months)	Mandrel unit	Replace O-rings on <ul style="list-style-type: none"> <li>- Connection piece in mandrel holder</li> <li>- Mandrel</li> <li>- Mandrel hood</li> <li>- Mandrel hood insert (replace disc spring set as well!)</li> <li>- Shaft</li> </ul>	<ul style="list-style-type: none"> <li>☞ O-ring *Appendix II-43</li> <li>☞ Disc spring *Appendix IV-43</li> </ul>
		Connection block: Replace guide bushes and guide rings	☞ *Appendix IV-43
		Mandrel hood interlocks <ul style="list-style-type: none"> <li>- Disassemble</li> <li>- Clean</li> <li>- Relubricate v-guides</li> <li>- Guides</li> </ul>	<ul style="list-style-type: none"> <li>☞ V-guide *Appendix II-43</li> <li>Grease Tribol Mollub-Alloy 9830-2</li> </ul> <p>Carry out together with cleaning of die plate!</p>
	Sterile area	Aseptic valves (V-valves): Replace membranes and sealing discs (where present) on irregularly used aseptic valves	<ul style="list-style-type: none"> <li>☞ Membranes</li> <li>Diagram No. 946081-188-0100,</li> <li>*Appendix II-81</li> <li>Manufacturer instructions *Appendix IV-81</li> </ul>

## For Blow-Fill-Seal:

➤ How to do (when, what, **with** )



Original  
**OPERATING INSTRUCTIONS**  
Version 1.2 dated 07. November 2016



### 6.3.3 Tools and materials

When carrying out maintenance work, only use

- Tools that are in perfect working condition and suitable
- Lubricants that are in perfect working condition and suitable
- Original replacement parts or parts explicitly approved by the company **rommelag**®.

#### Overview of supplied tools



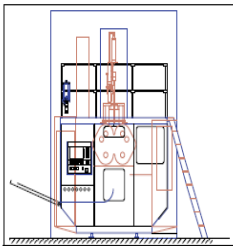
Fig. 6-2 Tool set

## For Blow-Fill-Seal:

➤ How to do (when, what, **with** )



Original  
**OPERATING INSTRUCTIONS**  
Version 1.2 dated 07. November 2016



No	Description	Purpose	Part No.
1	Open end wrench set		
10	Torque wrench 8-40 Nm with insert AF6	e.g. for assembly of moulds (25 Nm)	1543067 1543075 1396595
11	Warning sign - Do not switch on		
12	Wire brush 0.3 stainless		1204025
15	Assembly paste Rivolta G.W.F.		2227614
16	Assembly paste Rivolta F.L.A.		2285495
17	Grease - liquid grease BEL- RAY no-tox HD (BEL-RAY)		2554933

# Organization of Maintenance

## 2. Inspection- and Maintenance SOP

SOP

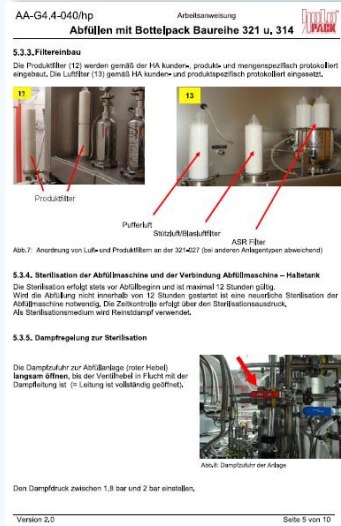
Inspection

Maintenance

and Servicing

of BFS

Type YXZ



For and after Production

Weekly Inspection

Monthly Inspection

Half yearly / Yearly  
Maintenance

# Organization of Maintenance

## 2. Inspection- and Maintenance SOP

SOP  
Inspection  
Maintenance  
and Servicing  
of BFS  
Type YXZ

### Example

AA-R2.1-012/hp A02 Arbeitsanweisung

Wartung der Bottelpack-Maschine

**Anlage 2 Wartungsprotokoll (wöchentliche Wartungen)**

Jahr	2018		X = Durchgeführt		W = Wechsel	
Masch. Nr.	321 850		P = Geprüft		-- = Entfällt	
Aufsicht	H. Hauer					

Woche	1	Datum / Signum	2	Datum / Signum	3	Datum / Signum	4	Datum / Signum	5	Datum / Signum	6	Datum / Signum	7	Datum / Signum
1	P	2018-01-10	X	2018-01-10	W	2018-01-10	-	2018-01-10	P	2018-01-10	P	2018-01-10	P	2018-01-10
2														
3														
4														
5														
6	P	2018-02-12	X	2018-02-12	W	2018-02-12	-	2018-02-12	P	2018-02-12	P	2018-02-12	P	2018-02-12
7	P	2018-02-19	P	2018-02-19	X	2018-02-19	P	2018-02-19	-	2018-02-19	W	2018-02-19	X	2018-02-19
8	X	2018-02-26	P	2018-02-26	W	2018-02-26	W	2018-02-26	W	2018-02-26	P	2018-02-26	X	2018-02-26
9														

2018-02-05 *CPH* NO Production



# Organization of Maintenance

## 2. Inspection- and Maintenance SOP

Arbeitsanweisung

Wartung der Bottelpack<sup>®</sup>-Maschine

### Wartungsprotokoll ( Weekly Maintenance )


X = done       W = changed  
 P = checked       - = Not applicable

1 / Signum	2	3 Datum / Signum	4	5 Datum / Signum	6	7 Datum / Signum	8	9 Datum / Signum	10	
01-10 GFA	W	2017-01-10 GFA	-	2018-04-10 GFA	P	2017-01-10 GFA	P	2017-01-10 GFA	P	2017-01-10 GFA
2017-02-05 GFA NU Prodruc (117)										

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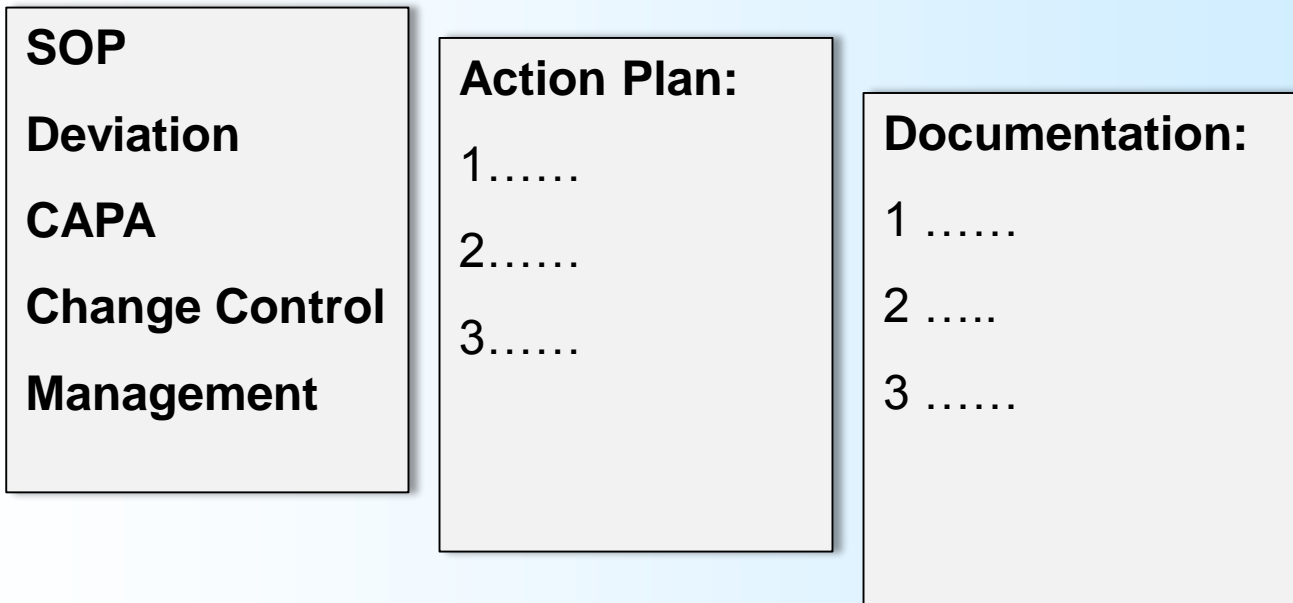
# Organization of Maintenance

## **3. (Corrective- and preventive) Actions**

- What action is allowed during service and maintenance?
- Action plan and time schedule
- Deviation and Change Management, CAPA System
- Risk analysis and approval for repair and changes

# Organization of Maintenance

## 3. (Corrective- and Preventive) Actions



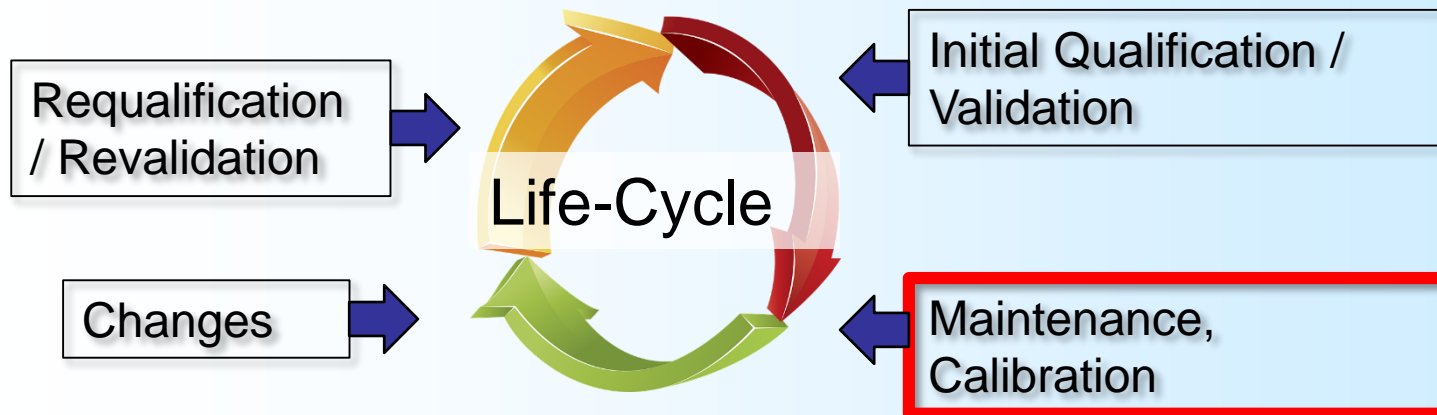
# Organization of Maintenance

## 4. Monitoring / Trending / Analysis

- Identify problems from following data resources:
  - Inspection and Maintenance records
  - Log book
  - Online Monitoring and Trending ( force, torque, velocity, ... )
  - Calibration
  - Deviations and Changes
- Problem solving technics like FMEA, Ishikava-Diagram, Roote-cause analysis ....
- Solve problems permanently
- Regular reporting of maintenance results

## Summary: Target of Maintenance

- Keep premises and equipment in good conditions
- Reduce risks of desaster – be preventive
- Understand the Life-cycle concept



**Thank you for your attention!**

**Please feel free to ask**

**Christoph Bohn**

Director Pharma Service

Senior Technical Consultant

[Christoph.Bohn@rommelag.com](mailto:Christoph.Bohn@rommelag.com)

