

[Organization logo]

[Organization name]

Commented [9A1]: All fields in this document marked by square brackets [] must be filled in.

PROCEDURE FOR PRODUCTION OF CHEMICAL PRODUCTS

Commented [9A2]: If you want to find out more about the product realization process, see:

- article: ISO 9001:2015 clause 8.5 Product realization – Practical examples for compliance

<http://advisera.com/9001academy/blog/2015/11/03/iso-90012015-clause-8-5-product-realization-practical-examples-for-compliance/>

- free online course: ISO 9001 Foundations Course

<http://training.advisera.com/course/iso-90012015-foundations-course/>

Commented [9A3]: Adapt to the existing practice in organization.

Code:	
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Distribution list

Commented [9A4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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1. Purpose, scope and users

The purpose of this procedure is to describe the process of production of chemicals according to demanded quantity and deadlines, in line with the request for product quality, according to customer request.

The procedure is applied in realization of the production process.

Users of this document are persons responsible for the process of production in [organization name].

2. Reference documents

- ISO 9001:2015 standard clauses 8.5; 8.6
- Procedure for Document and Record Control
- Procedure for Competence, Training and Awareness
- Procedure for Purchasing and Evaluation of Suppliers
- Procedure for Design and Development
- Warehousing Procedure
- Procedure for Management of Nonconformities and Corrective Actions
- Procedure for Equipment Maintenance and Measuring Equipment
- [Working instruction manuals]

Commented [9A5]: List the names of instruction manuals used in this process.

3. Product realization

3.1. Product realization planning

3.1.1. Making production plan

According to demand of products and volume of production in previous period, [CEO] together with [job title] creates [Production Plan].

Commented [9A6]: E.g. Production Manager

[Production Plan] defines the following:

- *Availability of information that defines product characteristics*

[Redacted text block]

Commented [9A7]: E.g. Product Specification, law and regulatory requirements, instructions, catalogues, etc.

Commented [9A8]: Delete if there is no cyclic production.

Commented [9A9]: E.g. Customer Request, Project Task, etc.

Commented [9A10]: Delete if organization doesn't perform this type of production.

- *Defining resources for production and service provision*

[job title] defines all resources needed for production, including human resources,

[Redacted text block]

[Job title] creates the Quality Plan, which defines necessary activities of verification, monitoring, measuring, controlling and testing the product.

Commented [9A11]: E.g. Production Manager

- Availability of [redacted]

[Job title] is responsible for [redacted]

Commented [9A12]: Working instructions are needed for more complex activities that have precisely defined order of execution operations and/or appropriate measuring is needed. They can be in form of Quality Plans, Flowcharts, drawings, etc.

- Usage of [redacted]

[Job title] is responsible to ensure that all equipment is in operational condition and, on [job title]'s request, deliver evidence of execution of the Plan for Preventive Equipment Maintenance and records of calibration and repairs of measuring equipment.

Commented [9A13]: E.g. Maintenance Operator

Commented [9A14]: E.g. Production Manager

[redacted]

Commented [9A15]: E.g. Head of maintenance department

- Conducting measuring and monitoring

[Job title] must ensure availability of monitoring and measuring resources and define the method of the monitoring process and product and methods of sampling and measuring and enter them into the Quality Plan.

Commented [9A16]: E.g. Production Manager, Technology Engineer, etc.

Commented [9A17]: Other records can be defined as addition to Quality Plan, e.g. records for monitoring temperature, pressure, humidity, etc.

3.1.2. Creating work order

For each individual batch, [job title] creates [Work Order] which defines all activities to be executed during production, responsibility for each activity, deadline, as well as raw materials needed.

[redacted]

Commented [9A18]: E.g. Production Plan, Customer Request, Project, etc.

Commented [9A19]: E.g. Production Manager

Commented [9A20]: Delete if clause 8.3 of ISO 9001:2015 is excluded.

Commented [9A21]: E.g. Warehouse Manager

Commented [9A22]: E.g. Production Manager

Commented [9A23]: E.g. Production Manager

3.2. Production provision realization

Production is executed in controlled working conditions, which implies compliance with all technical [redacted]

Commented [9A24]: This refers to law and legal requirements.

3.2.1. Internal purchase and receipt of raw materials

According to the Production Plan and Production Registry, [job title] makes internal purchase. After receipt of demanded raw materials, [job title] inspects [redacted]

3.2.2. Production of plastic semi-product

Commented [9A25]: Adapt to organization practice.

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[job title] receives the raw plastics in form of as granules, pellets, or powder. The raw plastic is then

3.2.3. **Reacting the raw materials**

Based on Product Specification, [job title] feeds the hopper with raw materials while [job title]

3.2.4. **Filtration**

[job title] pours the compound into a filter in order to remove any trace levels of catalyst. If the catalyst is not removed then

3.2.5. **Concentration**

The compound is heated under vacuum, which evaporates off some of the water, increasing the

3.2.6. **Granulation**

[job title] pours the compound on the one side and the seed granules on the other side into granulator which sprays molten working solution onto seed granules which are supported on a bed

[job title] oversees the removal of all

3.2.7. **Packaging and storing**

[job title] oversees the packaging process and in case of nonconformities apply Procedure for Managing Nonconformities and Corrective Actions. Once the product is finished [job title] sends it to warehouse for final products.

3.2.8. **Identification and traceability**

[Job title] must identify the product through the entire production process and define methods of identification and enter them in the Record of Traceability.

3.2.9. **Validation of production and service provision**

[Job title] must conduct validation of all processes of chemicals production where

- it is not possible to confirm

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Commented [9A29]: Adapt to organization practice.

Commented [9A30]: Adapt to organization practice.

Commented [9A31]: E.g. serial number, Working order ID, bar code, software ID, expiring date, production date, labeling, accounting documentation, etc.

Commented [9A32]: Or Production Registry.

Commented [9A33]: Delete if there are no processes that require validation; see Quality Manual.

Commented [9A34]: For example

[organization name]

- It is not possible to conduct measurement, since product or service is being destroyed in the process

Where appropriate, as part of validation, [job title] must determine:

- Criteria for review and approval of process
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Commented [9A35]: This is entered in Quality Plan.

Commented [9A36]: This is entered in Quality Plan.

Commented [9A37]: This is done when previous validation didn't give expected results.

Commented [9A38]: Adapt to organization.

[Job title] creates records needed to provide evidence that realization processes and resulting products meet predefined requests.

[Redacted]

3.2.10. Customer property

Commented [9A39]: This can be deleted if organization doesn't use Customer Property. See Quality Manual.

[Job title] is responsible for identification, verification, and protection of customer or external provider property that is given for use or implementation in a product. If customer or external provider property is

3.2.11. Control of changes

[job title] reviews and controls changes for production in order to ensure continuing conformity with the requirements and enters changes in the Production/Service Change Review Record.

3.2.12. Product release, delivery and activities after delivery

[Job title] is responsible for determining, at appropriate stages, by which degree the product requirements are met regarding Product Specification and customer requirements. If requirements are met,

[Redacted]

[job title] ensures that the release of products and services to the customer will not proceed until

[Redacted]

[Job title] defines the extent of post-delivery activities that are required, considering:

- Statutory and regulatory requirements
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

[organization name]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

During servicing activities, [job title] is obligated to initiate correction of non-conformance using the Procedure for Managing Nonconformities and Corrective Actions for [redacted]

Commented [9A40]: Adapt to organization's needs.

3.3. Product preservation

[Job title] is responsible for preservation of product during production and internal transport of product and/or assembly parts.

Commented [9A41]: This should be deleted if organization is only service oriented.

Commented [9A42]: E.g. Production Manager

[redacted]

Commented [9A43]: E.g. Warehousing Manager

[redacted]

Commented [9A44]: E.g. Driver

3.4. Resolving non-conformities

If a non-conformity of process or product occurs, the person who discovered the non-conformity notifies [job title], who acts according to the Procedure for Control of Non-Conforming Product.

[redacted]

Commented [9A45]: E.g. Shift Leader

4. Managing records kept on the basis of this document

Record name	Code	Storage			Responsibility
		Retention time	Location	Protection	
Product Specification	PR.10.1	2 years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Record of Product/Service Conformance	PR.10.2	2years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]

Commented [9A47]: Adapt the information in this column to the normal practice in your company.

Commented [9A46]: Adapt the information in this column to the normal practice in your company.

Commented [9A48]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A49]: If the record is in electronic form, write the name of the folder on Production Manager computer.

[organization name]

Quality Plan	PR.10.3	2years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Notification to a Customer about Changes on his Property	PR.10.4	2years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Record of Traceability	PR.10.5	2 years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Production/Service Change Review Record	PR.10.6	2 years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Production Plan	PR.10.7	2 years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Production Registry	PR.10.8	2 years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]

Commented [9A50]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A51]: This document is unnecessary if organization doesn't store and work with customer property.

Commented [9A52]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A53]: If the record is in electronic form, write the name of the folder on Production Manager computer.

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Commented [9A56]: If the record is in electronic form, write the name of the folder on Production Manager computer.

5. Appendices

- Appendix 1 – Product Specification
- Appendix 2 – Record of Product/Service Conformance
- Appendix 3 – Quality Plan
- Appendix 4 – Notification to a Customer about Changes on his Property
- Appendix 5 – Record of Traceability
- Appendix 6 – Production/Service Change Review Record
- Appendix 7 – Production Plan

[organization name]

- Appendix 8 – Production Registry