Supplier Quality Requirements
(the “Requirements”)

In the framework of ARXADA’s vendor qualification process, the present quality commitment is required to be accepted by any SUPPLIER, including new and existing vendors. By accepting the purchase order released by ARXADA, the SUPPLIER agrees to comply with the content of this document.

A) If the SUPPLIER is not the manufacturer of the PRODUCT, the SUPPLIER undertakes to:

- Ensure that the manufacturer(s) comply with the Requirements outlined in this document;
- Provide ARXADA with the name and address of the manufacturer;
- Declare the origin of each batch, if more than one manufacturer is producing the PRODUCT;
- Obtain prior approval from ARXADA before subcontracting manufacturing to any new producer.

B) If the SUPPLIER is the manufacturer of the PRODUCT, SUPPLIER undertakes to:

1. Operate a Quality Management System (QMS), such as ISO 9001 or an equivalent standard, or will have in place systems and procedures to ensure the quality of the PRODUCT and services as required by ARXADA, as further outlined in Annex 1 “Responsibilities”.

   Within this system, SUPPLIER undertakes to maintain and document the necessary qualifications of personnel involved in PRODUCT operations and PRODUCT release. This includes ensuring that all individuals performing operations on the PRODUCT and overseeing PRODUCT release are fully aware of their role in ensuring PRODUCT or service conformity.

   Where applicable, SUPPLIER will only use raw materials and quality-critical services from ARXADA’s approved providers and will inform these external providers of the quality requirements set forth by ARXADA for raw materials and services, including any relevant customer-specific requirements.

   The use of counterfeit materials or components will be actively prevented through appropriate processes established by SUPPLIER.

2. Promptly notify ARXADA’s Quality Assurance team of any changes defined in the Change Control Agreement for PRODUCTS used in specific industries, such as PHARMA, AEROSPACE, FOOD/FEED, and COSMETICS, and obtain prior approval from ARXADA before shipment.

3. Ensure complete traceability of the PRODUCT to the raw materials used and maintain comprehensive batch documentation.

4. For multipurpose equipment, ensure documented cleaning procedures are followed before beginning the manufacture of the PRODUCT**.**

5. Deliver the PRODUCT in compliance with the packaging and delivery conditions agreed upon with ARXADA, and in accordance with the relevant SDS and PRODUCT information, to ensure the PRODUCT is protected from damage during shipment.

6. Include on the label the SUPPLIER’s name, manufacturing location address, PRODUCT name in English, storage conditions, net weight, and any other relevant information required for the PRODUCT, the applicable industry, or by ARXADA.

7. Take all required measures during the packaging, storage, and shipping of the PRODUCT to prevent any deterioration, contamination, or mix-ups with other materials.
8. Determine retest dates (or expiration dates, if applicable), as well as storage and shipping conditions, based on stability studies or documented historical data.
9. Provide each batch of PRODUCT in accordance with its specifications, along with a CoA (Certificate of Analysis) or, if applicable, a CoC (Certificate of Conformity). The CoA must include the manufacturing date, release date, and expiry/retest date.
10. Store retention samples of the PRODUCT, enough for at least two full specification tests, in containers that provide equal or better protection than the commercial packaging. These samples will be kept for one year after the batch's expiry date, or as set by the SUPPLIER.
11. Store the original batch records and all other documents related to the manufacturing of the PRODUCT in a safe place to prevent loss or unauthorized access. These records will be kept for one year after the batch's expiry date and SUPPLIER will provide access to these records to ARXADA during on-site audits.
12. Inform ARXADA Quality Assurance team of any restrictions on the manufacturing license, particularly if any legal action has been taken against the SUPPLIER.
13. Allow ARXADA representatives, ARXADA customers, and/or relevant authorities to perform periodic and for-cause audits of the facilities involved in the production, storage, and distribution of the PRODUCT. During these audits, access to all premises will be provided, and quality system documentation related to the PRODUCT's manufacturing will be available for review.
14. Ship any PRODUCT to ARXADA until it is confirmed to meet the agreed specifications OR unless ARXADA's Quality Assurance team has given prior written approval to ship it under quarantine. Where applicable, apply statistical methods for material approval in accordance with ARXADA's acceptance criteria and instructions.
15. All chemical or measurement reference standards used to release the PRODUCT must be stored according to the SUPPLIER's recommended conditions and used before their specified expiry or retest date.
16. Not to change the PRODUCT specifications without prior written approval from ARXADA and, upon request, provide ARXADA with the necessary information and methods used to qualify the proposed changes.
17. Ensure that the shipping agent complies with ARXADA's delivery conditions for dispatching the PRODUCT to ARXADA. If special handling is required, such as refrigerated storage, these additional requirements must be clearly marked on the external packaging, pallets, and containers.
18. Ensure that the correct transport conditions are maintained throughout the journey from the manufacturer, through the supply chain, to ARXADA.
19. Provide ARXADA with the updated Safety Data Sheet (SDS) whenever a new version is released.

ARXADA will immediately inform the SUPPLIER about any changes to these Requirements.

Annex 1: Responsibilities

L = ARXADA; S = SUPPLIER

A Regulatory Compliance		**L**	**S**
	Adhere to approved registration documentation (Marketing Authorisation etc, as applicable)		X
	Maintaining valid manufacturing license(s), as applicable		X

B Purchasing, Manufacturing and Analytical Testing of Raw Materials, Process Aids, Intermediates, and PRODUCT		**L**	**S**
	Setting specifications for **PRODUCT**	X	X
	Qualifying and monitoring material and supplier		X
	Storing retention samples		X
	Documenting all deviations, investigating OOS and critical deviations		X
	Maintaining (certified) reference standards		X

C Storage and Shipment		**L**	**S**
	Storing **PRODUCT** under labeled conditions	X	X
	Maintaining storage conditions during transportation until agreed transition point		X

D Documentation		**L**	**S**
	Archiving the original manufacturing and control documents		X
	Preparing reports on OOS, critical deviations		X
	Providing test procedures, quality statements, stability reports, and other documents as mutually agreed between the parties		X
	Control and monitoring performance i.e. KPIs		X
	Personal qualification of all employees		X
	Training instructions for all employee (incl. ethical behaviour) and retraining process		X
	Retain all documented information as defined in QMS		X

E Production, Equipment Cleaning, maintenance and calibration		**L**	**S**
	Prevent any contamination of **PRODUCT**. Appropriate cleaning of equipment to avoid cross contamination.		X

F	Qualification / Validation	L	S
	Qualifying of equipment, utilities and facilities where appropriate		X

G	Stability Program	L	S
	Assigning retest or expiry date to **PRODUCT**		X

H	Complaints	L	S
	Investigating customer complaints related to **PRODUCT**		X
	Implementing corrective actions, if necessary		X
	Responding to customer(s)		X
	Clarifying root cause		X

I	Sub-Contracting	L	S
	To inform **ARXADA** before subcontracting manufacturing or part of the manufacturing process of **PRODUCT** to any subcontractor		X
	Qualifying and monitoring of sub-contractors		X