JGL'S EXPERTISE IN THE DEVELOPMENT AND PRODUCTION OF SEAWATER-BASED PHARMACEUTICAL PRODUCTS

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EXPERTISE IS DRIVEN BY A VERTICALLY INTEGRATED PROCESS

Sourcing of Seawater
Seawater quality control
Finished product manufacturing

LEGAL FRAMEWORK

- Seawater quality → defined in EU Directive 2000/60/EC: The Water Framework Directive
  - Legal framework for the protection and improvement of the quality of water resources
- JGL is a pharmaceutical manufacturer → procedures in line with Good Manufacturing Practice (GMP)
  - GMP requires a set framework for Quality management
- Purified seawater is used in medicines → EMEA QWP/39695½006
  - Specification set in line with quality requirements for non-pharmacopoeial excipients, such as purified sea water

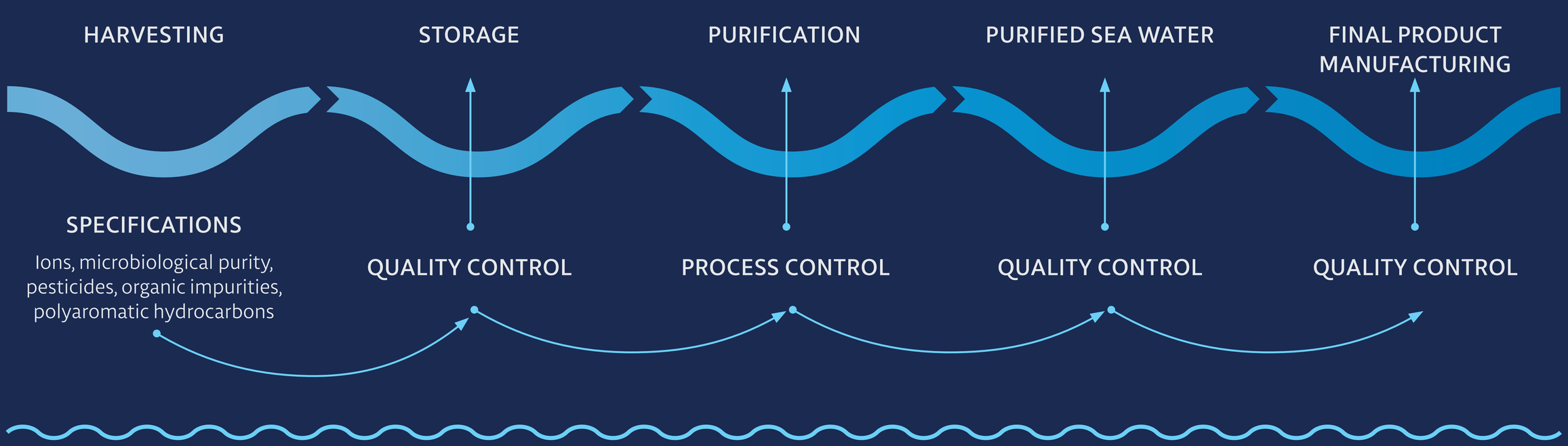
SOURCING SEAWATER

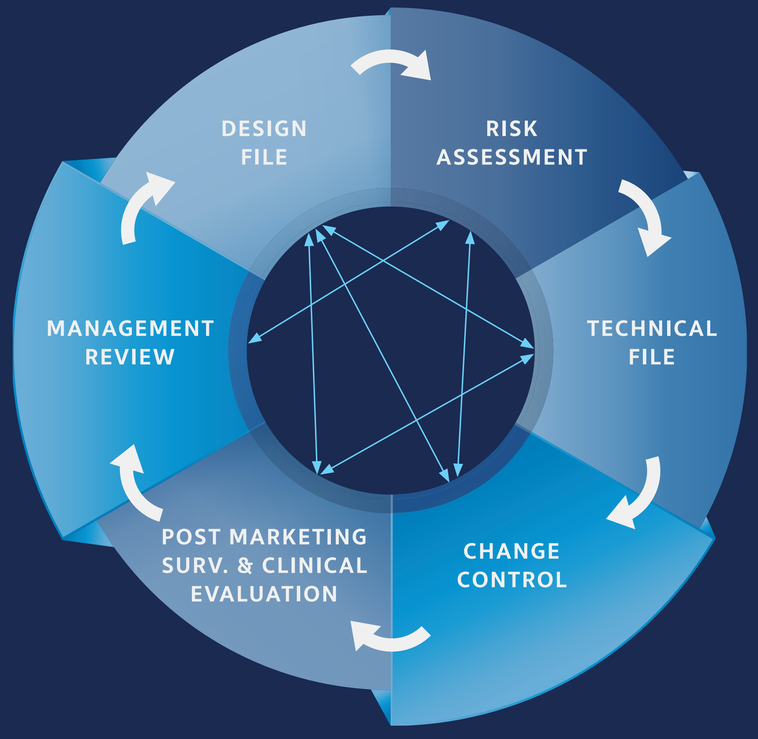
Sourcing location is set and monitored.
Sourcing depth is set with scientific research.
Operations follow procedures set in line with GMP.

CHARACTERISTICS OF SOURCING LOCATION

Away from settlements.
Away from industry.
Only seasonal fishing and maritime transport.

MANUFACTURING PROCESS OF PURIFIED SEA WATER



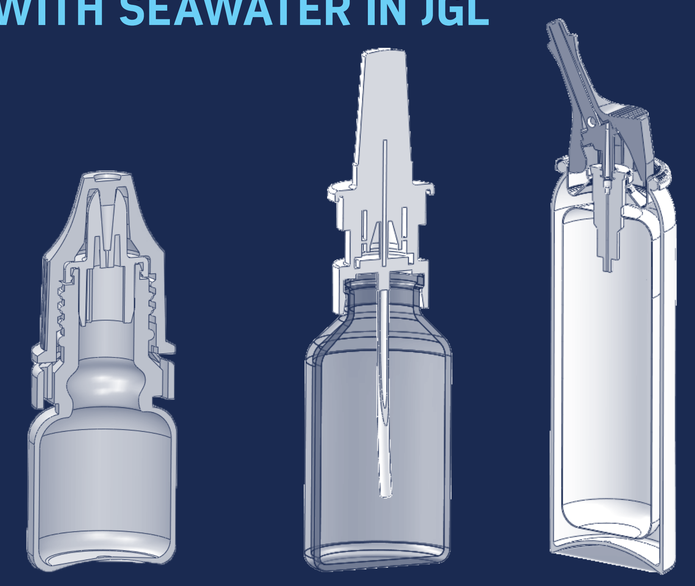


FINISHED PRODUCT DEVELOPMENT

- Development for Medical Devices: ISO 13485 and EU Directive: EU 2017/745
- Development consists of: design and setting of quality target product profile, formulation development, production process development, stability monitoring, preparing of technical documentation and submission to the Certification Authority

20 YEARS AQUA MARIS

TYPES OF MEDICAL PRODUCTS WITH SEAWATER IN JGL



Dropper bottle | Spray bottle | BOV