LUINABIO
BIOPHARMACEUTICAL MANUFACTURING

# ISO Standards for the Fermentation & Isolation of Medicinal Products

LuinaBio's 1200m$^2$ facility is located in the suburb of Darra south of the Brisbane's central business district (CBD). This facility is comprised of a series of modular clean room laboratories with ISO 8 fermentation suites and support areas. Purification and final product isolation suites are ISO 7 cleanrooms.

## Our ISO Class 8 manufacturing room for microbial fermentation performed under cGMP conditions features:

- Fermenters from 5L development reactors to 500L production vessels
- Continuous tubular bowl centrifuges
- Millipore ultrafiltration housings and associated equipment
- Stokes stoppering shelf Lyophiliser (50L condenser capacity)
- Stainless steel process tankage to 600L
- Bioprocess chromatography system
- Chromatography columns to 200L
- 150L temperature and pressure synthesis reactor
- Biohazard hoods
- USP grade purified water system
- Clean steam system
- Clean steam Autoclave
- Compressed air
- Vacuum
- Chilled glycol loop

## LuinaBio's ISO Class 7 purification room performed under cGMP conditions features:

- Fermentation (batch, fed batch and continuous)
- Continuous centrifugation
- Ultrafiltration
- Membrane filtration
- Reverse osmosis
- Chromatography
- Homogenisation
- Lyophilisation
- Hydrolysis
- Synthetic reactions

The fermentation and isolation suites described above are also supported by a ISO 8 storage areas ranging from -80°C to controlled ambient temperatures for raw material, in process material, and finished product.

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## Meaning of the above ISO classifications:

The classification of air cleanliness is very simple as the class equates to the number of particles of a particular size (e.g., 0.5, 1 or 5 µm particles) per cubic micrometer of air.

An ISO Class 8 clean room is the eight classification type of the ISO 14644-1 and the environment within the room is about 100,000 times cleaner than natural air. Measuring the concentration of airborne particles, ISO 8 requires less than 29,300 particles sized larger than 5 micrometers per cubic meter of air, no more than 832,000 particles sized less than 1 micrometer per cubic meter of air and fewer than 3.52 million particles sized less than 0.5 micrometer per cubic meter of air. Class 8 clean rooms don't regulate particles smaller than 0.5 micrometers.

Each ISO class represents a ten-fold difference in cleanliness. For example, an ISO 3 room will be ten times "cleaner" than an ISO 4 room. See table below:

**Table 1: Airborne Particulate Cleanliness Classes (by cubic meter)**

| CLASS | Number of Particles per Cubic Meter by Micrometer Size | | | | | |
|---|---|---|---|---|---|---|
| | 0.1 um | 0.2 um | 0.3 um | 0.5 um | 1 um | 5 um |
| ISO 1 | 10 | 2 | | | | |
| ISO 2 | 100 | 24 | 10 | 4 | | |
| ISO 3 | 1,000 | 237 | 102 | 35 | 8 | |
| ISO 4 | 10,000 | 2,370 | 1,020 | 352 | 83 | |
| ISO 5 | 100,000 | 23,700 | 10,200 | 3,520 | 832 | 29 |
| ISO 6 | 1,000,000 | 237,000 | 102,000 | 35,200 | 8,320 | 293 |
| ISO 7 | | | | 352,000 | 83,200 | 2,930 |
| ISO 8 | | | | 3,520,000 | 832,000 | 29,300 |
| ISO 9 | | | | 35,200,000 | 8,320,000 | 293,000 |

## What does the above ISO designations mean for our clients?

LuinaBio's use of ISO health standards provides tools to assess and evaluate conformity and ensures consistency for our clients. ISO standards safeguard consumer interests by ensuring good quality care and safe and reliable products and services. Regulators can rely on these trusted internationally harmonized solutions, which are continually reviewed and improved to provide a technical basis for market-friendly regulations that meet citizens' expectations. In addition, ISO standards are strategic tools whereby we give our clients the ability to gain a competitive advantage through products and services that are safe, reliable and trustworthy.

## *Contact Us*

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