



# How to move from small to full scale production?

# HCM Medical Contract Manufacturing Services

## Contract Manufacturing

A large demand exists for a contract manufacturing organization with the expertise needed to easily get familiar with the production process of a (bio)medical innovation, and besides has the right licenses that allow for production of these products according to the applicable regulations.

### Products or services:

- **Production of products for customers** within the current regulations:
  - Medical Devices (**ISO13485**)
  - Pharmaceuticals (**GMP for IMP products**)
  - Weefsel (human) (**IGJ, EU Tissue Directive**)
- **Development of new products** in collaboration with the customer, within the possibilities and expertise
- **Production**, on behalf of the customer, the first batches after product development for clinical studies or product registration under MDR/GMP.
- **Provide support** in the field of test method development
- **Production (process) validation**
- **Product registration under MDR.**

#### Development

Support in production and feedback in product development

#### Registration

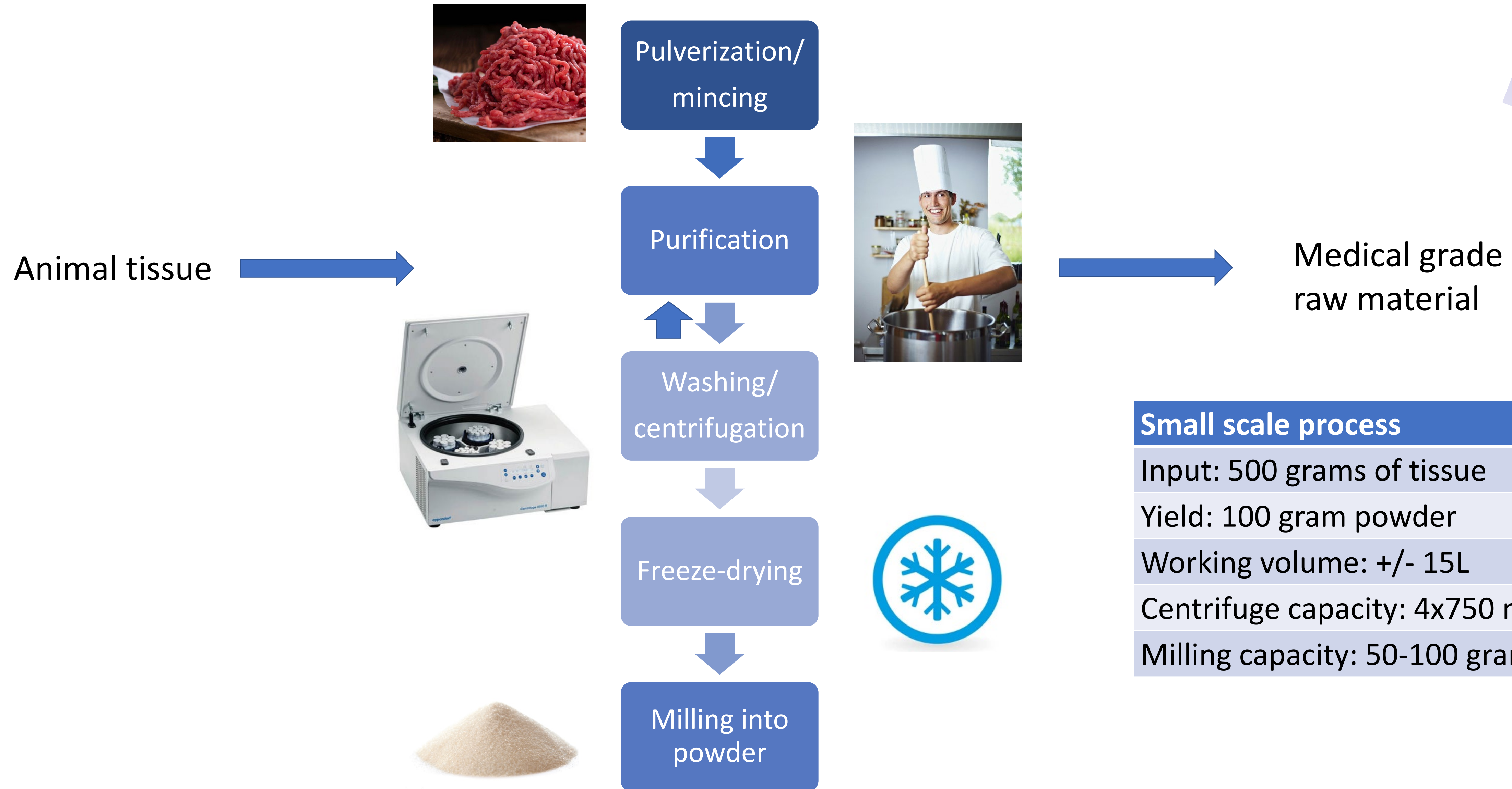
Support and feedback in regulatory processes

#### Commercialization

Production, packaging and distribution

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# Small scale production process



## Small scale process

Input: 500 grams of tissue

Yield: 100 gram powder

Working volume: +/- 15L

Centrifuge capacity: 4x750 mL / 10 min

Milling capacity: 50-100 grams/day



# Large scale production process?



- Do you have experience in scaling up production processes?
- What are the challenges?
- Where to find the experience?
- What are the common pitfalls?
- What technologies/companies to look for?

**We are very interested in hearing and learning from your experiences!**

## Large scale process

Input: 50 kg of tissue

Yield: 10 kg powder

Working volume: +/- 400-600L

Centrifuge capacity: 400-600L/ 2h

Milling capacity: 5-10 kg/day