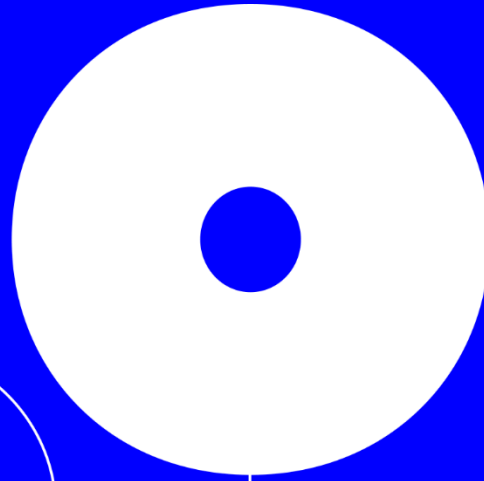


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NOVEMBER 2020



CONSIDERATIONS FOR
ADAPTING EXISTING FACILITIES
TO CHANGING VACCINE
DEVELOPMENT DEMANDS

B₁OEN₁NEER₁NG

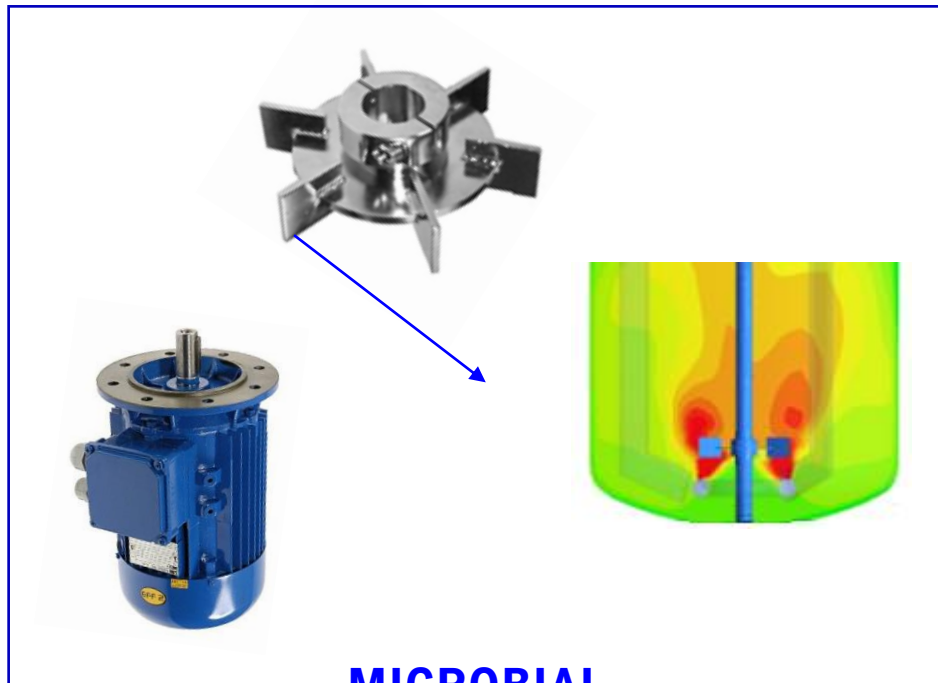
TECHNICAL ASPECTS

- Changing from one microbial process to another microbial process (or cell to cell) does not usually require major technical retrofitting
- Cell to Microbial culture is technically demanding
- Microbial to Cell culture technically *less* demanding

- Most important is:
 - ➔ identifying suitable agitation
 - ➔ supporting suitable aeration

AGITATION: ACHIEVING GENTLE AND EFFICIENT MIXING

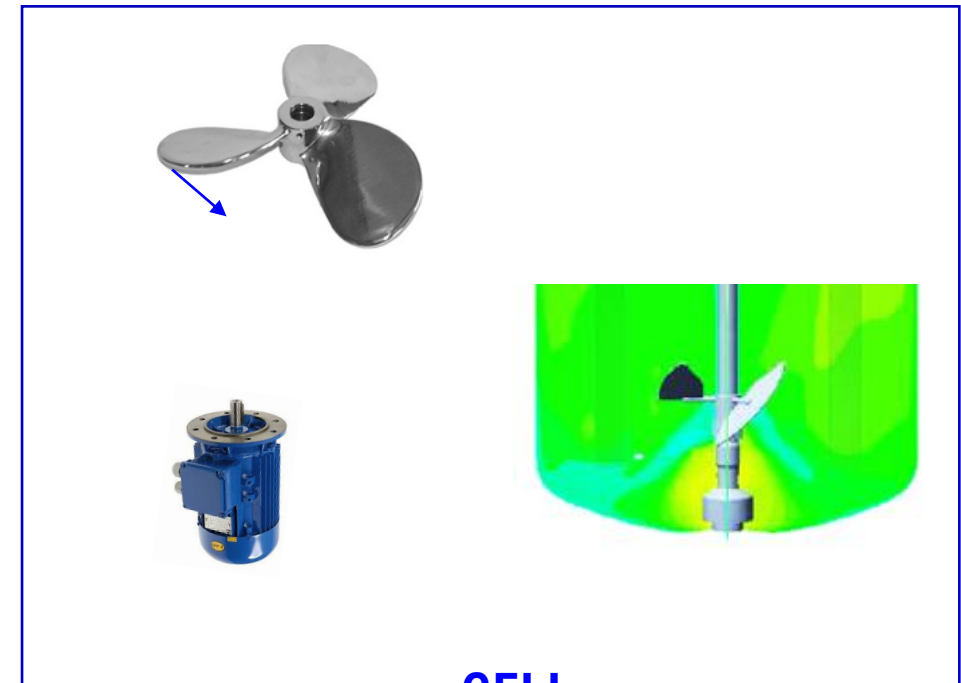
- Change of tip speed, power input and impact on shear forces might be necessary



MICROBIAL

Technically simple
→

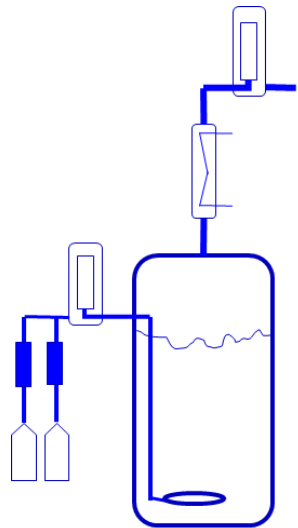
←
Technically demanding



CELL

AERATION: ACHIEVING THE DESIRED K_LA

- Change of piping, sparger, gas flow control and exhaust system might be necessary



MICROBIAL

Technically demanding

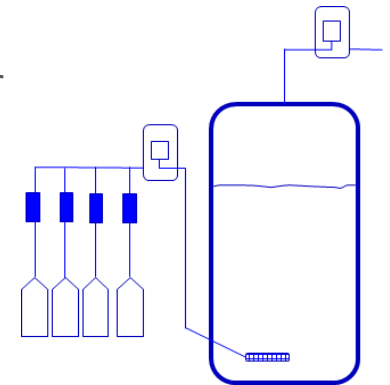


- Enlargement of the inlet and exhaust gas pipe diameter
- Installation of a condenser
- Larger gas flow controllers
- Larger gas filters

Technically simple



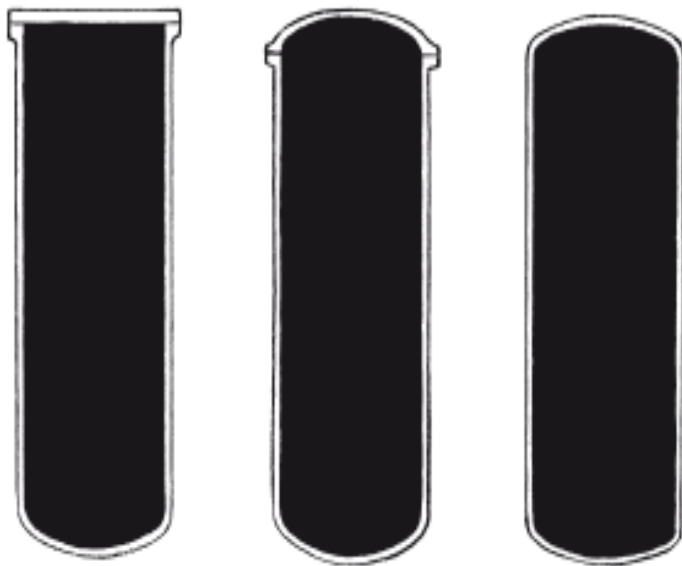
- Change from ring to microsparger
- Maybe change flow controller
- Additional gas lines



CELL

VESSEL GEOMETRY

- Vessel geometry is less critical than agitation and aeration
- While not optimal, you can get away with leaving it unchanged if required

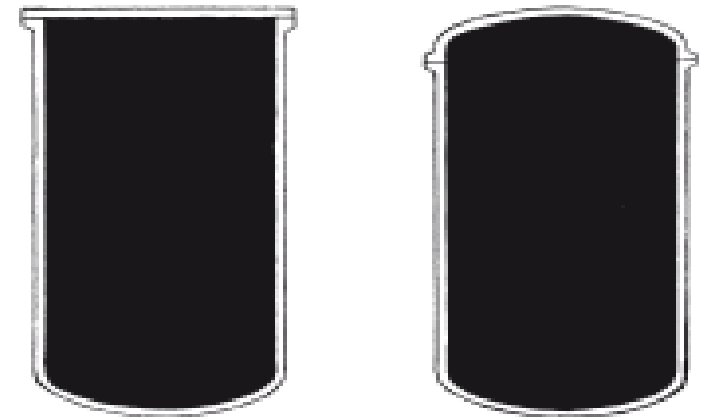


MICROBIAL

Although not optimal, microbes can be cultivated in wider, shorter cell-culture bioreactors



Cell cultures can usually be cultivated in taller, more slender fermentors without problems



CELL

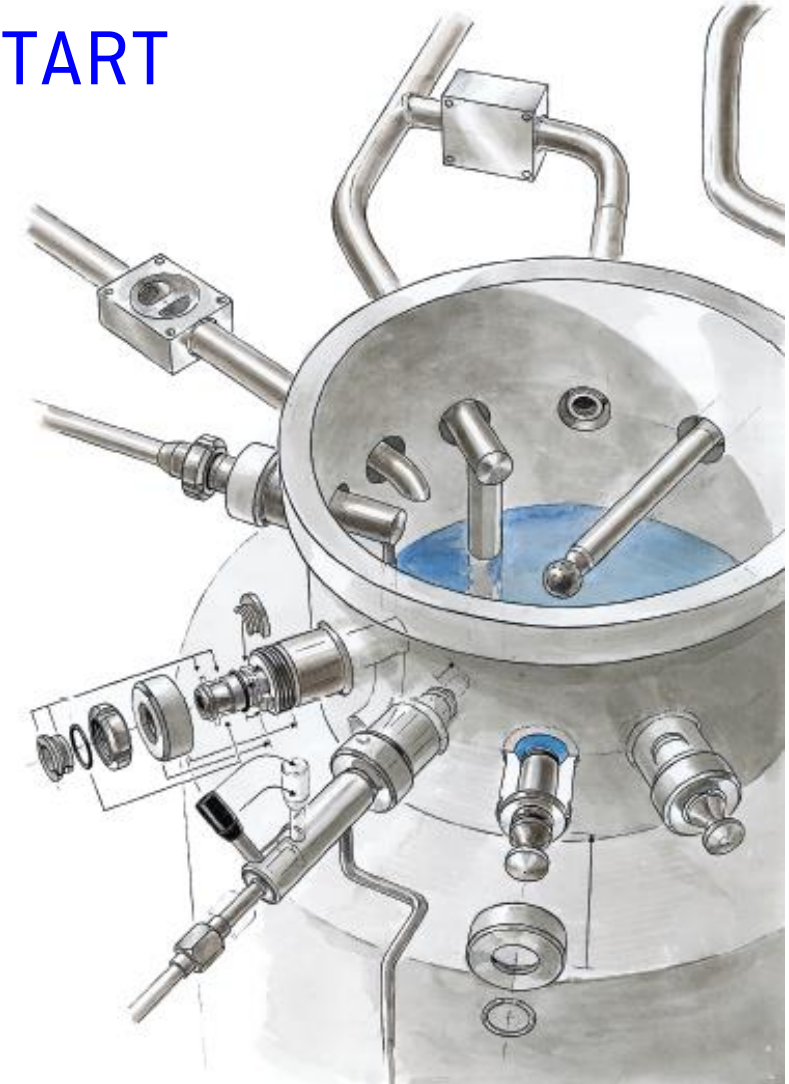
HYGIENIC ASPECTS

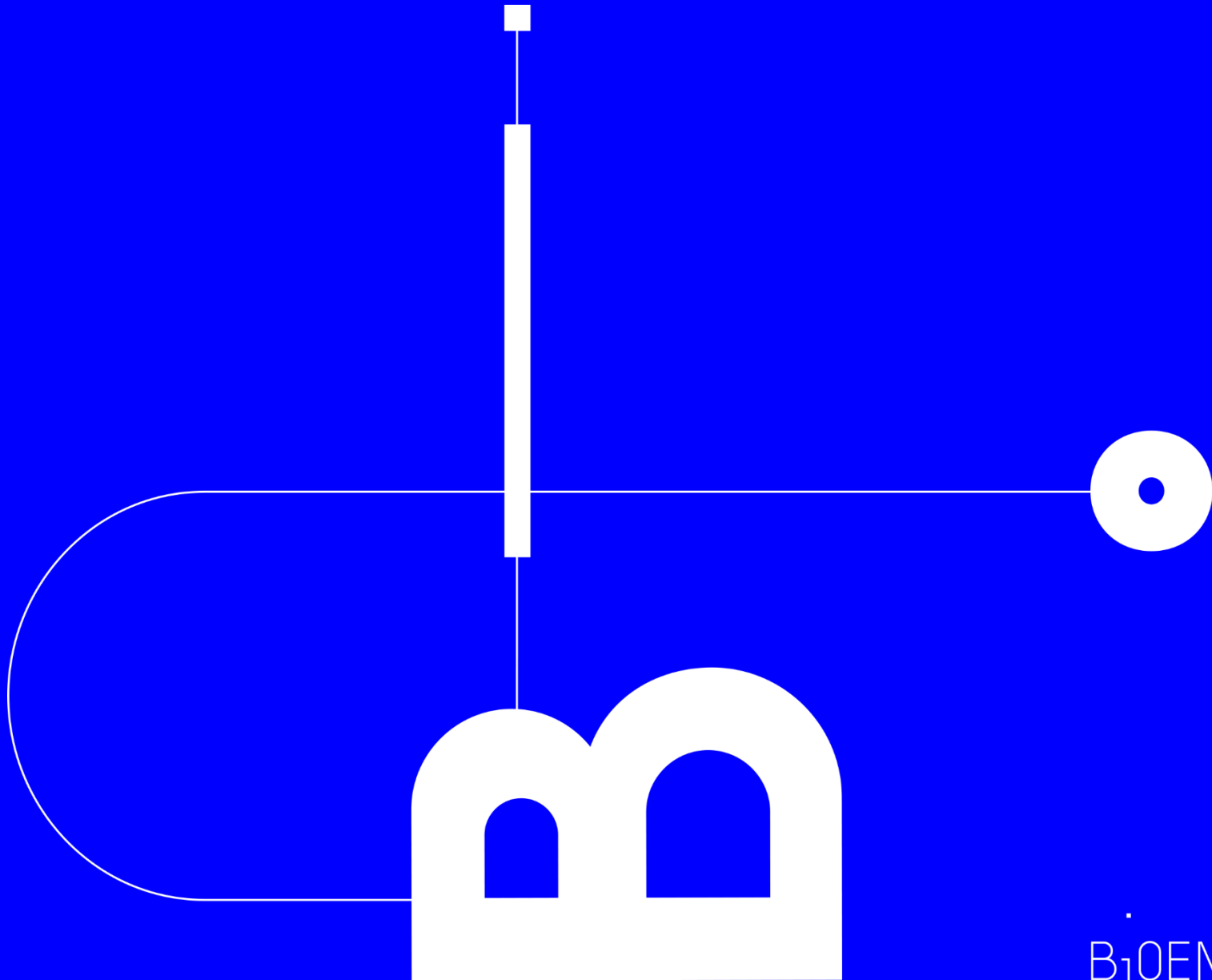
- Watch out for cross-contamination
 - From microbial to cell culture
 - From microbial to microbial
 - From cell culture to cell culture
 - *Reduced risk* when changing from cell to microbial
- ➔ An efficient and thorough CIP/SIP is essential
- ➔ Replacement of all seals and membranes is necessary



PLANNING FOR MULTIPLE PRODUCTS FROM THE START

- Software
- Agitation
- Aeration
- Vessel geometry
- Interfaces to DSP





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