#### FULLY cGMP **COMPLIANT PLANT**

**Located in Northern Italy** 

>350 Employees

Annual output

250 MT API & Intermediates

**Annual Reach** 

- >200 Customers
- >60 Countries

**Total reactors capacity** 

- 450 m<sup>3</sup>
- Total area

• 110.000 m<sup>2</sup>

#### **Broad Capability**

- From few Grams to MTs >30 multipurpose trains

#### **HIGH Potent**

#### Capability

- Fully segregated (from
- warehouse to waste treatment) **RD** and QC Laboratories on site
- Containment level down to 10 ng/m³ (Safebridge class 4)
- 2 cGMP lines from few grams to
- 15 Kg of API batch size

# Continuous technology improvement: key partnership to meet your outsourcing needs



#### 360° Small molecule **Service Provider**

#### - R&D

Route Scouting Safety Studies Process Chemistry Development Enhanced Optimization through QbD

Special Technologies:

- Crystallization Studies
- Wet Milling
- Flow Chemistry Analytical Development & Impurities Characterization

#### - QUALITY

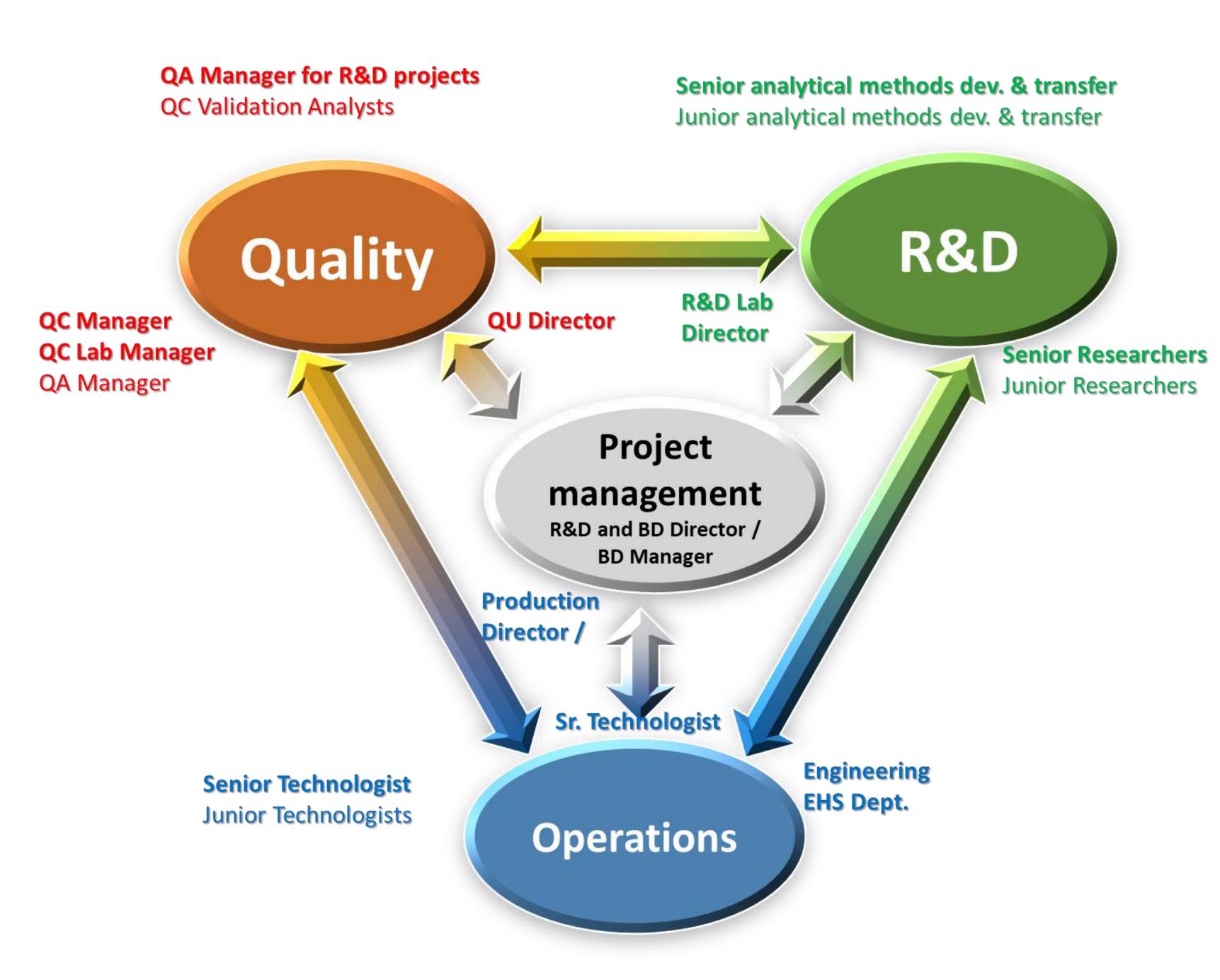
Analytical Methods Validation (Process & Cleaning) Any kind of Methodology State-of-the-art Instruments Regulatory Support to IMPD, IND, NDA

#### - MANUFACTURING

Broad Capability (from 25 L to 12000 L) High Potent API Facility on Site

## PROJECT MANAGEMENT

#### From Discovery (Preclinical) to Commercial: Supporting through all your development



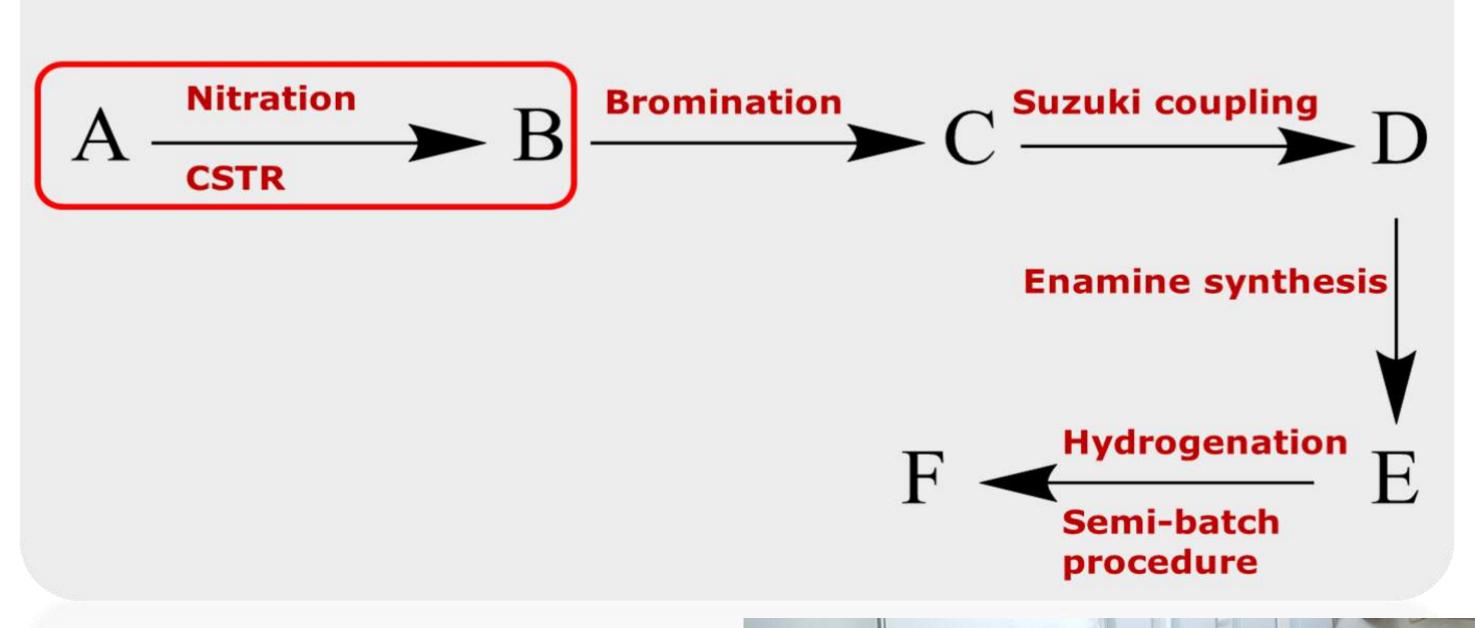
#### Connections between units R&D Quality CMC/ Project R&D Quality manager **BD** (Project management) Operations Connections between units Operations Procos

- > REAL TEAMWORKING (QUALITY/R&D/OPERATIONS) WITH CROSS-FUNCTIONAL APPROACH
- > IP DISCOVERED IN PROCOS IS FULLY BELONGING TO THE CUSTOMER
- > TRANSPARENCY
- > QUICK RESPONSE TO CUSTOMER NEEDS
- > FLEXIBILITY TO SUDDEN CHANGES IN CUSTOMER STRATEGIES → SCHEDULING

## Case 1 – Flow Chemistry Technology improvement by partnership

#### **Customer Request:**

- 5 Process Step for Phase I/II API intermediate to be implemented in manufacturing plant in 5 months:
- Flow chemistry and semi-batch hydrogenation to be designed and implemented
- Organometallic chemistry (highly sensitive and toxic reagent handling) PHASE I/II intermediate

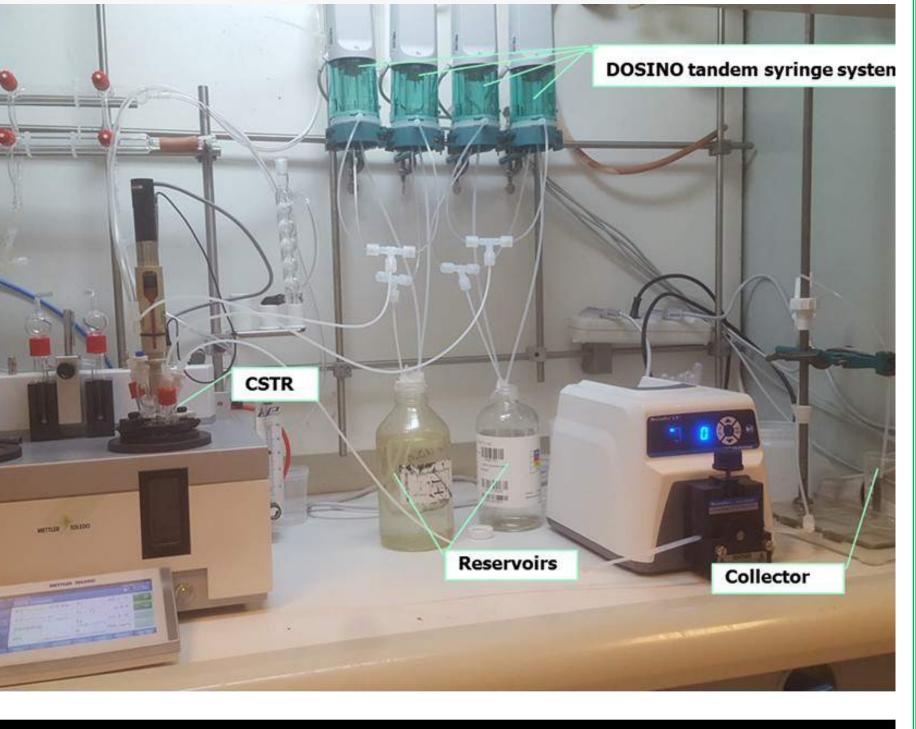


## Step 1 Mononitration of aromatic compound

## **Challenges:**

- Highly exothermic reaction Risk of multiple nitrations
- Heterogeneous mixture (formation of hot spots)
- Instable starting material in reaction condition **Solution:**

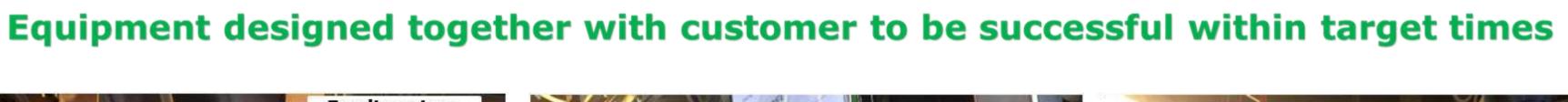
Continuous Stirred Tank Reactor (CSTR).

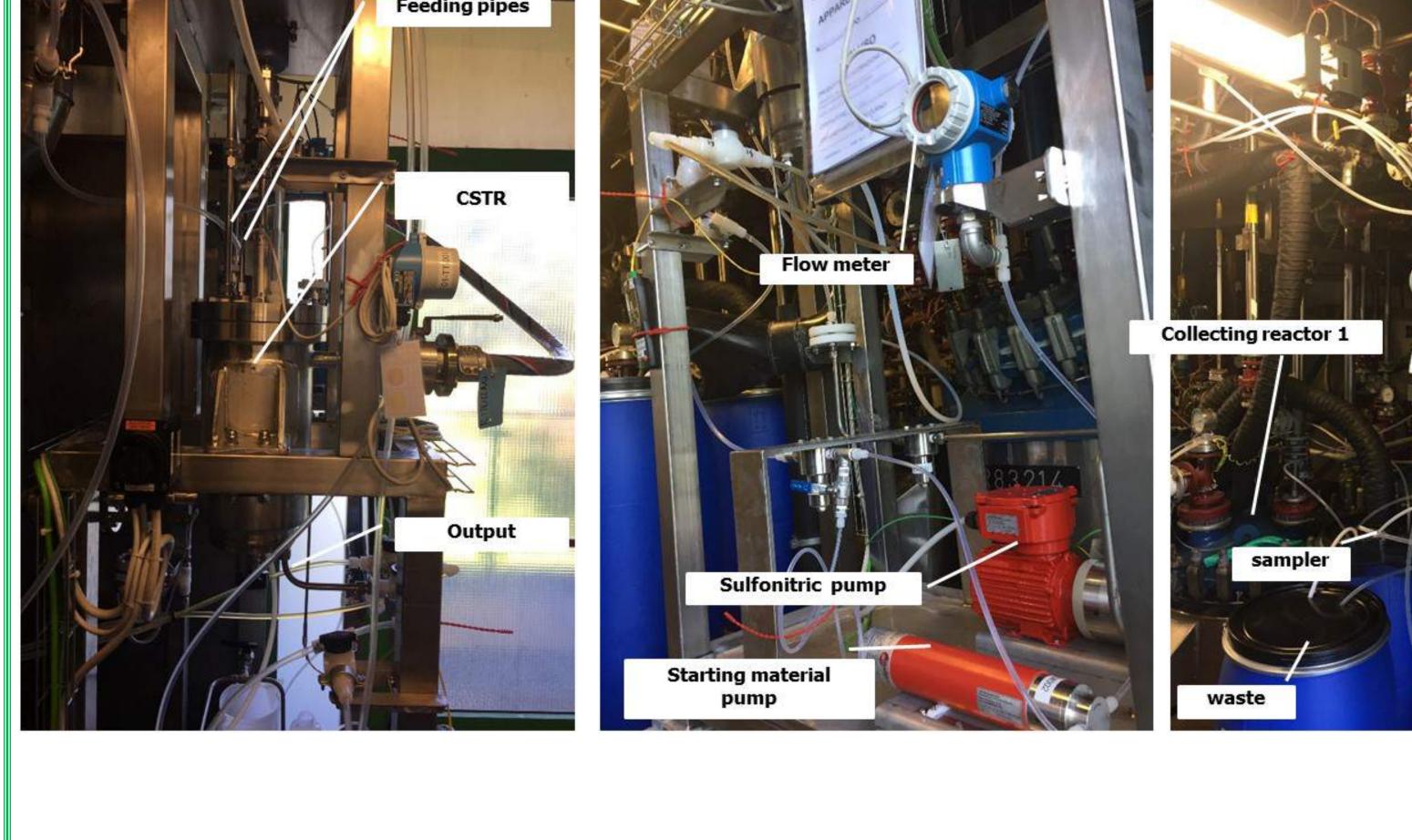


The lab scale CSTR allowed us to reach full conversion and high selectivity to the mono-nitrated product

## From Lab to Plant:

- Lab Scale: Manufacturing of 3 kg of nitrated mixture in 12 h by using 50 mL reactor
- Plant: Manufacturing of almost 30 kg/h of nitrated mixture (4kg/h of Product ) in 4 L **CSTR** reactor





Scale-up manufacturing completed in 2 months

Process feasibility and optimization in 3 months

Two new technologies implemented within 5 months

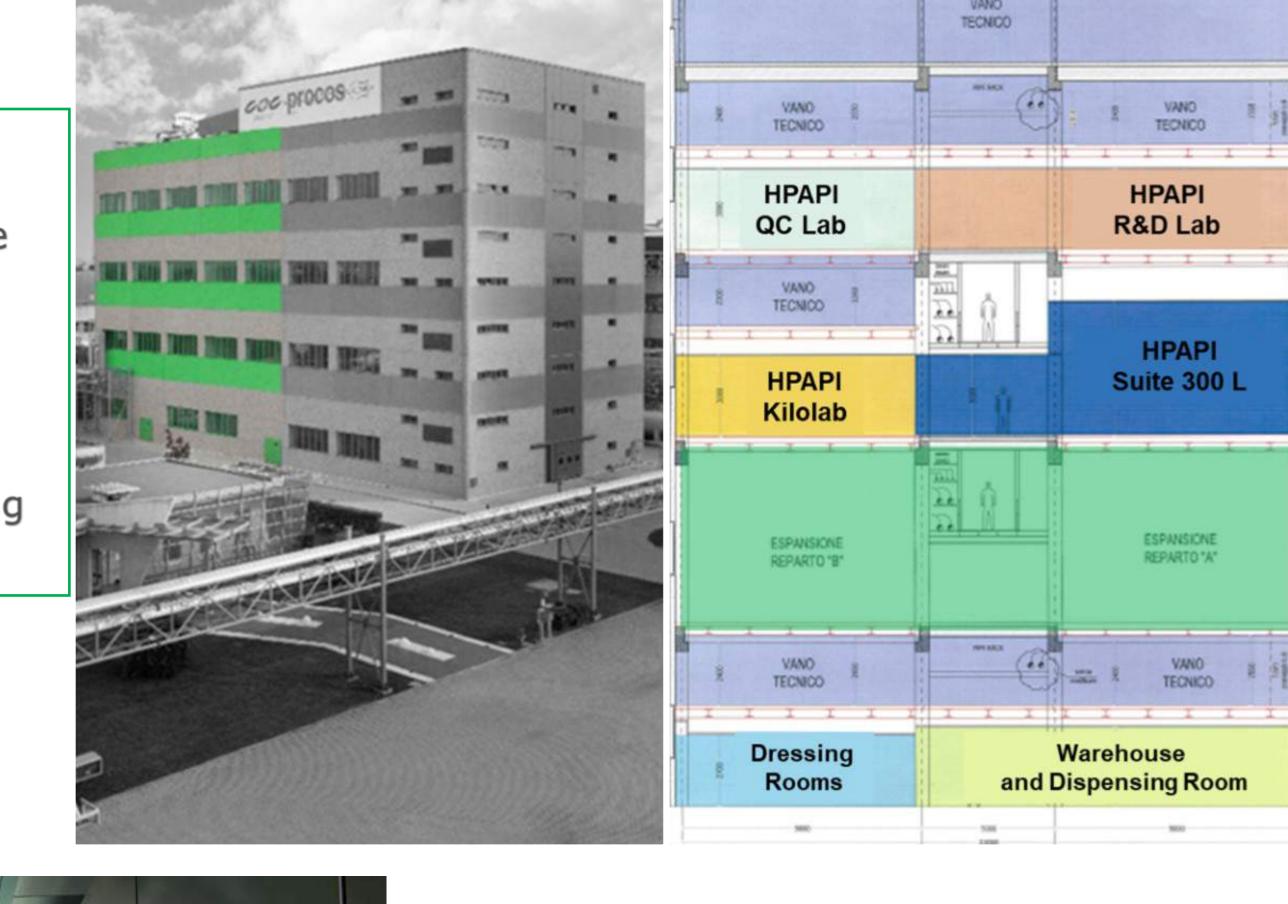
## Case 2— High Potency API unit Technology expansion by internal evaluation

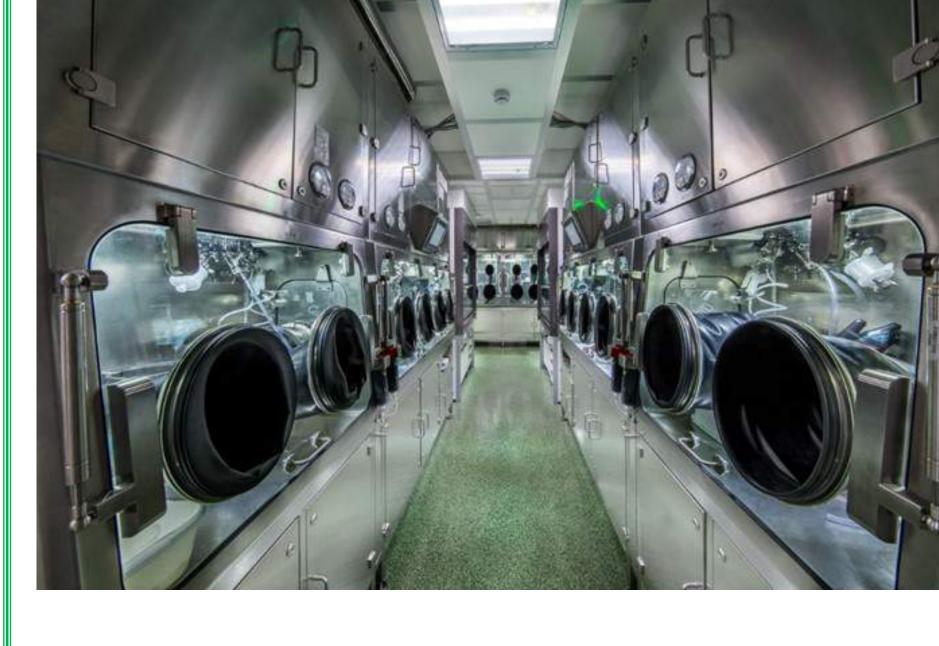
## To meet market needs and opportunities in the Highly Potent API field,

Procos built up a brand new unit

## Fully segregated unit:

- Independent Warehouse and waste treatment
- Dedicated RD and QC laboratories
- Two cGMP manufacturing trains



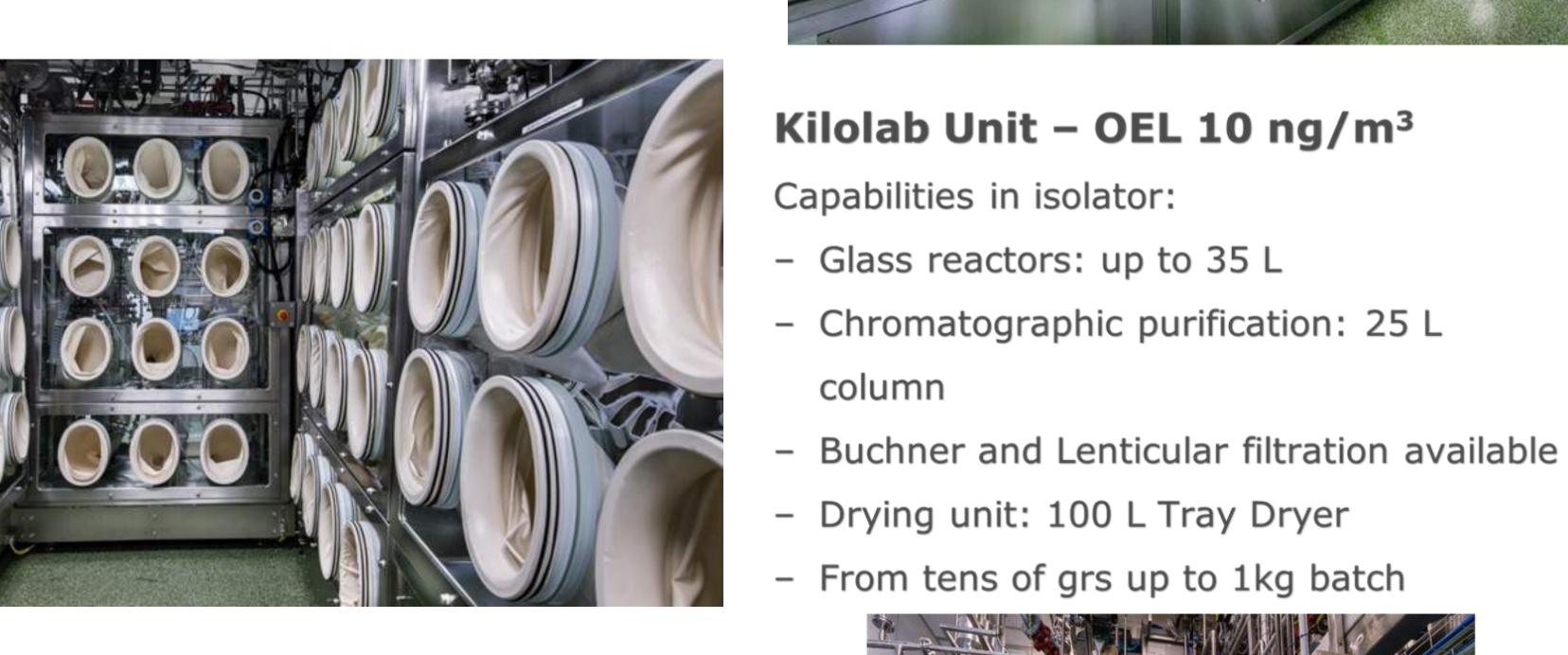


## R&D Unit – OEL 10 ng/m<sup>3</sup>

- Automated reactors: up to 400 mL Safety studies in isolator (e.g. Radex, Easymax)
- Chromatographic purifications in isolator
- Analytical development on site

## QC Unit – OEL 10 ng/m<sup>3</sup>

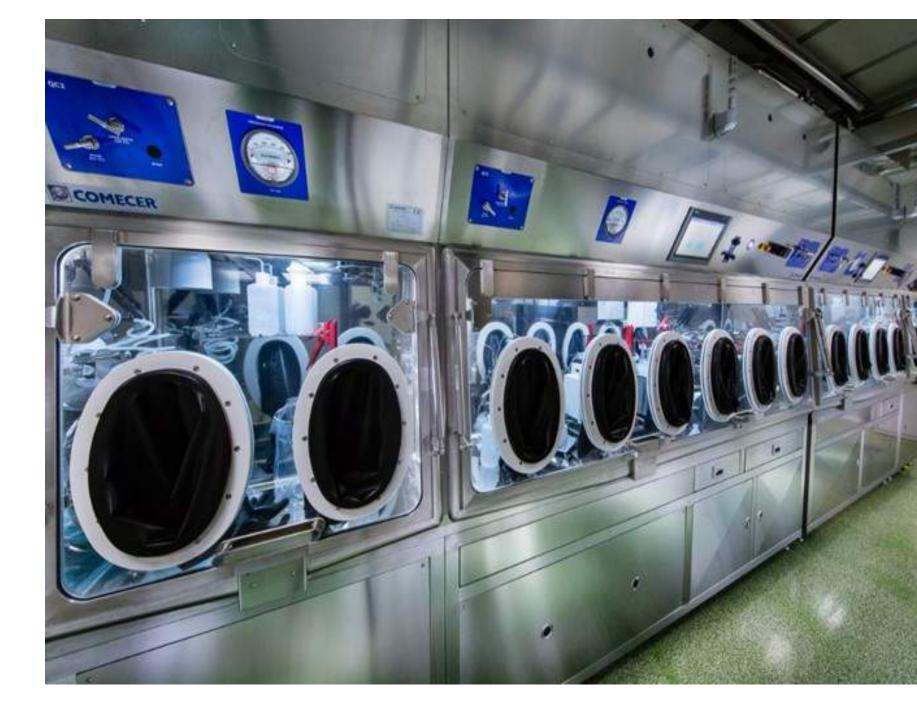
- All equipment for powder analysis in isolator
- All suitable instruments for releasing tests on site (PSD included)

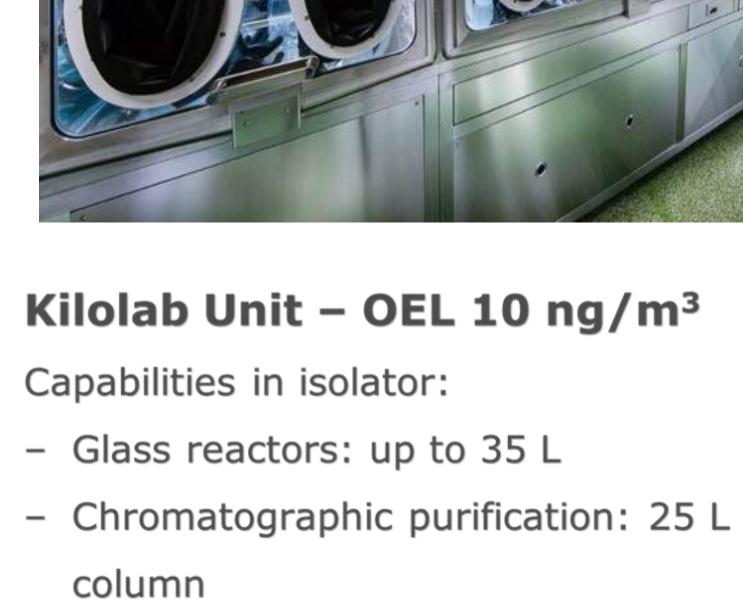


#### Small Scale Unit – OEL 1 µg/m<sup>3</sup> Capabilities:

## Hastelloy and Glass lined reactors: up to

- 300 L
- Chromatographic purification: 100 L column
- Filter dryer and Lenticular filtration available
- Between 5kg and 10kg batch







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