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All-Scale Manufacturing Solution for mRNA-LNP

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Co-Founder & CEO

BioTuesdays 7 Novembre 2023, Lyon, France

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> 12 000 000 000

Manufactured mRNA covid vaccine doses (2 products)

773

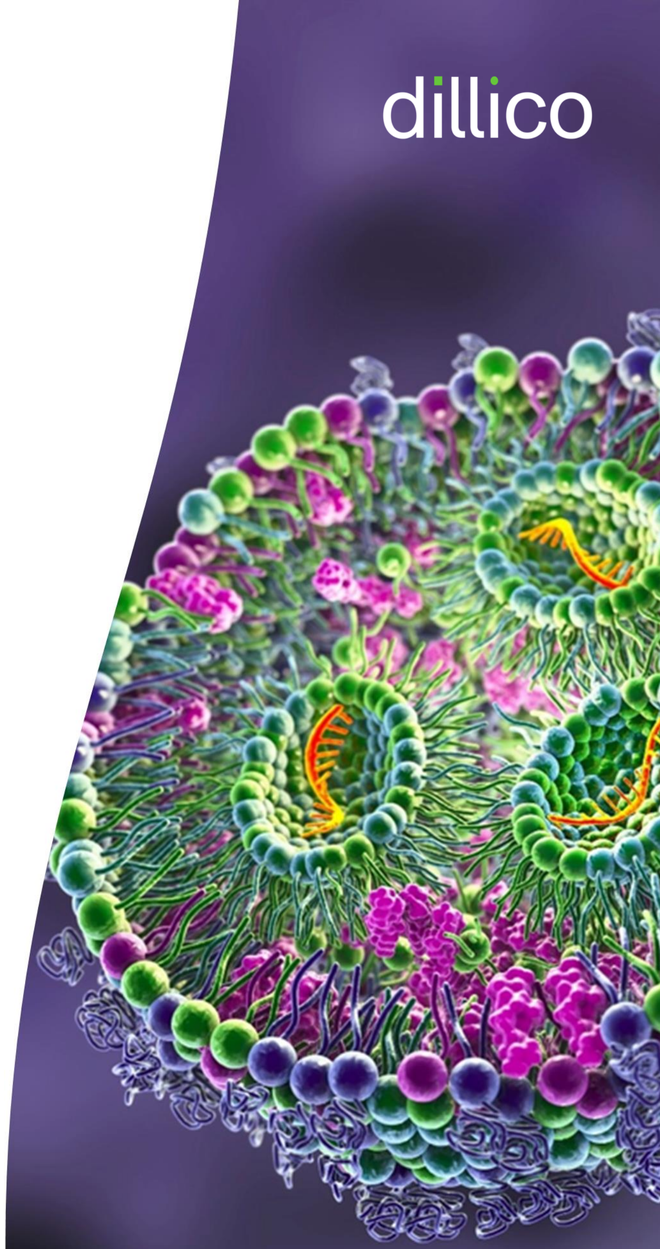
mRNA-LNP medecine candidates (pre-clinical to phase 3)

50 L **300 m²** **480 kg**

50L batch to be processed in a 300m² facility, 480 kg/day of plastic waste

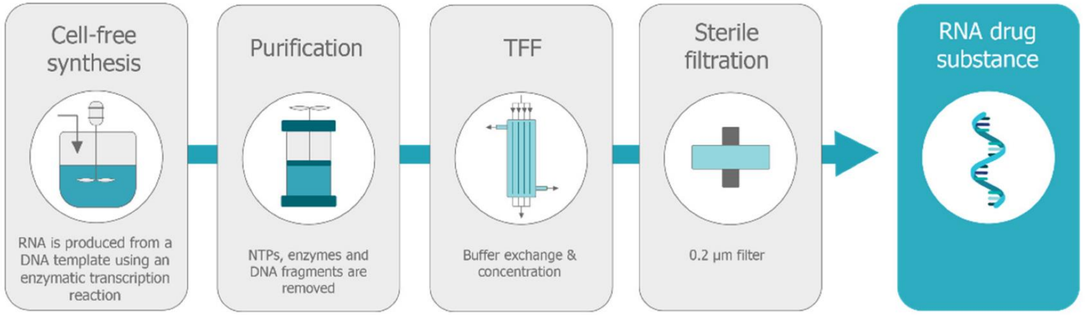
350 g

mRNA drug substance produced

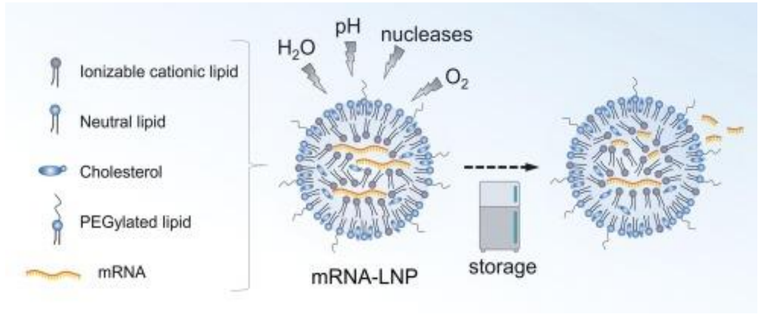


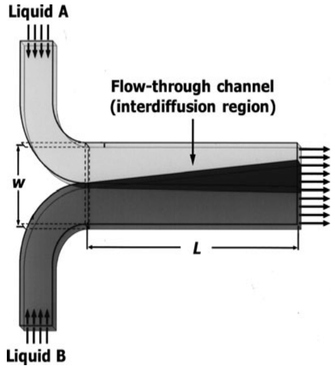
Manufacturing Process

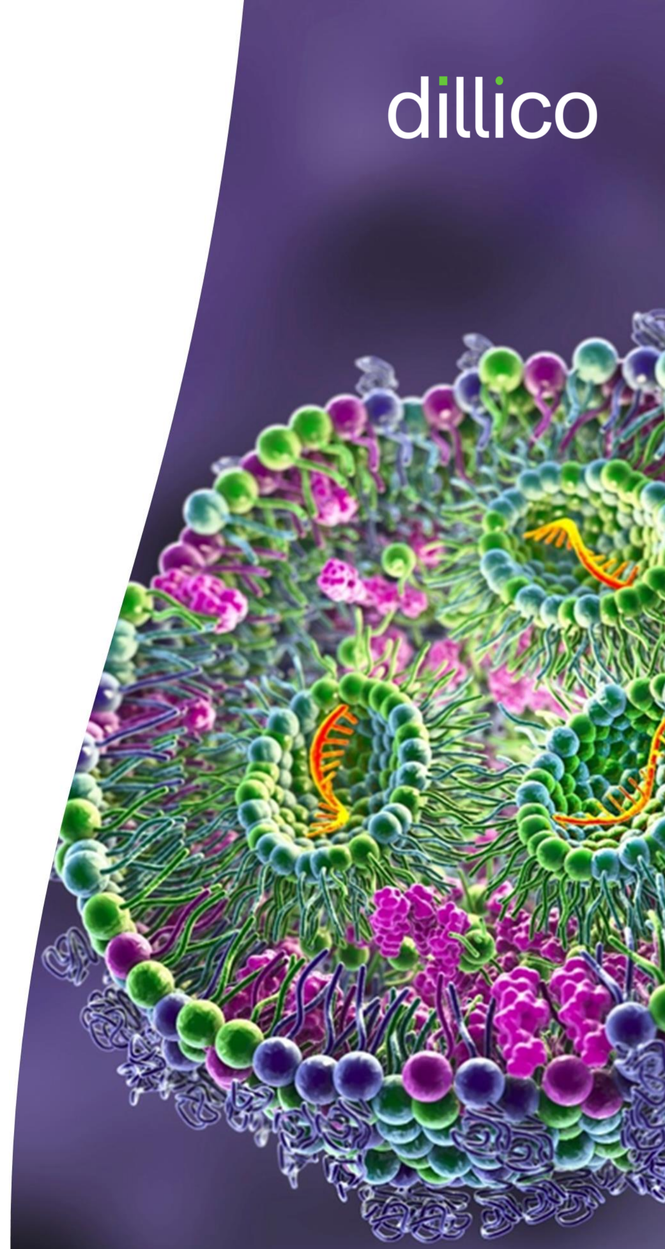
Drug Substance (DS): « naked mRNA »



Drug Product (DP): encapsulated mRNA

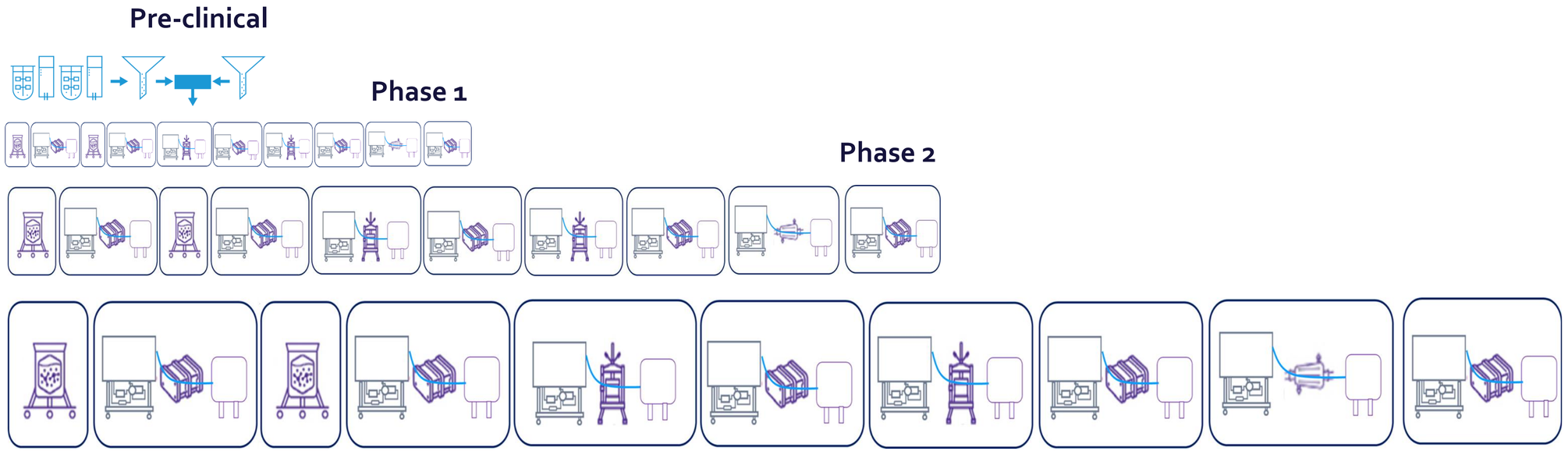






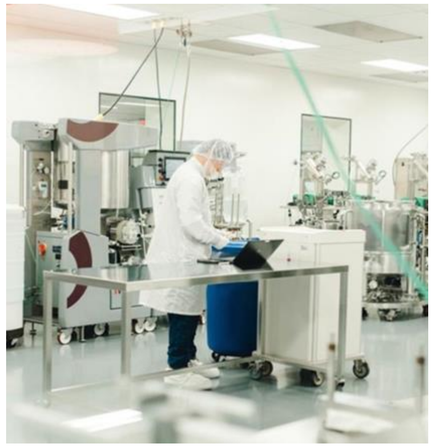
mRNA Batch manufacturing

Current Batch Process



Batch manufacturing with single-use skids

- Low yield
- 300 m² facility footprint to process a ~50L batch
- Deviations due to human errors & handling
- No flexibility of the production capacity
- mRNA degradation induced by process hold times
- Expensive scale-up activity at risk



Our solution.

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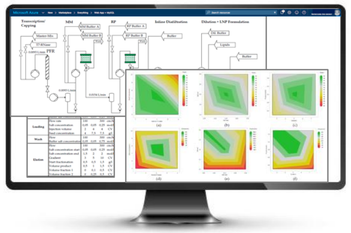
Continuous mRNA Manufacturing equipment and digital solution

Process & equipment Digital Twin



Hybrid modeling for
- Digital exploration of CM
- Digital process development

+

End-to-end mRNA-LNP continuous manufacturing equipment

All-ScaleFlow™ Technology on-board

+

Digital tools and services

Automation enables **remote & real-time**:
- Monitoring (customer side)
- Customer support
- Maintenance

All-ScaleFlow™ Patented Technology

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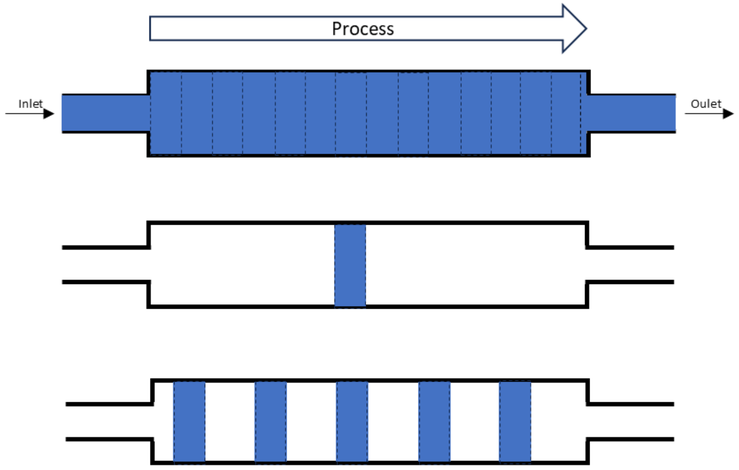
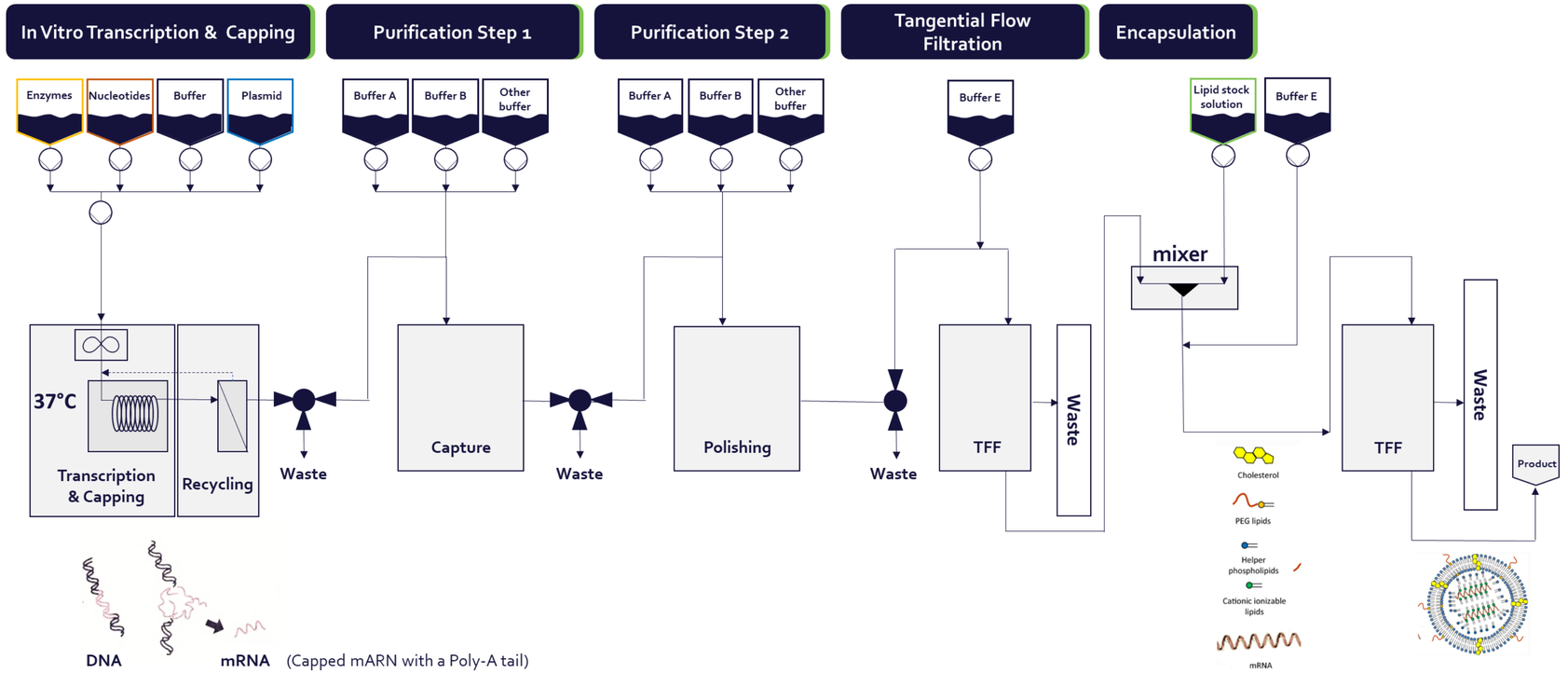
1 equipement &
1 process for all scales and clinical phases

In Vitro Transcription Volumes

Minimum	Maximum
1000 doses (eq. Vaccine)	1 Mo doses per run
~ 5 mL	5 L





Automation.

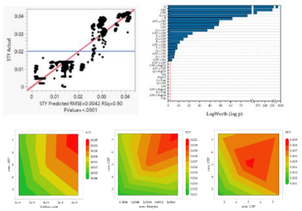
End-to-end integration around a steady state

Process Recipe

MES

Digital Twin Simulator

Models
Mini-batch data



Continuous process exploration & evaluation
Optimized DoE design

Equipment Control

PLCs
DCS

End-to-end unified data flow

Digitalized Process Control

Process control
APC (real-time automated set point change)

Quality Monitoring
IPC, real-time quality attribute (no full RTRT) => Diverted product

Process performance
Real-time analytics & monitoring, historian, Dashboard => alarm, manual improvement

Advanced support

Equipment & Process expert support
Based on shared data

Real-time maintenance
Preventive (blind failure prediction) and diagnostic

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Key differentiators.

as solution for mRNA manufacturers

Quality

Fully enclosed, monitored and digitalized process. No hold time

Direct Scale-up & Flexibility

1000 to 10+ million doses per run

Optimized Costs

COGS reduced by 80%

Regional Manufacturing

Automated 4 m² footprint equipment

Sustainability.

At the core of our solution

Recycling

Less Raw Material Cost

~15M€ saved per 10Mio doses

Waste Reduction

Less Single Use Plastic

Adjusted Reaction Volumes

-0.48T plastic saved per batch per day

Broad Accessibility

Less reliance on cold chain, supply chain and highly skilled operators

GHG Emission Reduction

Simplified logistic transport and cold chain

- 80% GHG Emission

FTE: full time equivalent
GHG: Green House Gas

The Company.

- **Setup in May 2022 in Grenoble, France**
- **Partnership with Pharma and mRNA key players (Afrigen and other non-disclosed companies)**
- **Grand Prix i-Lab 2023**

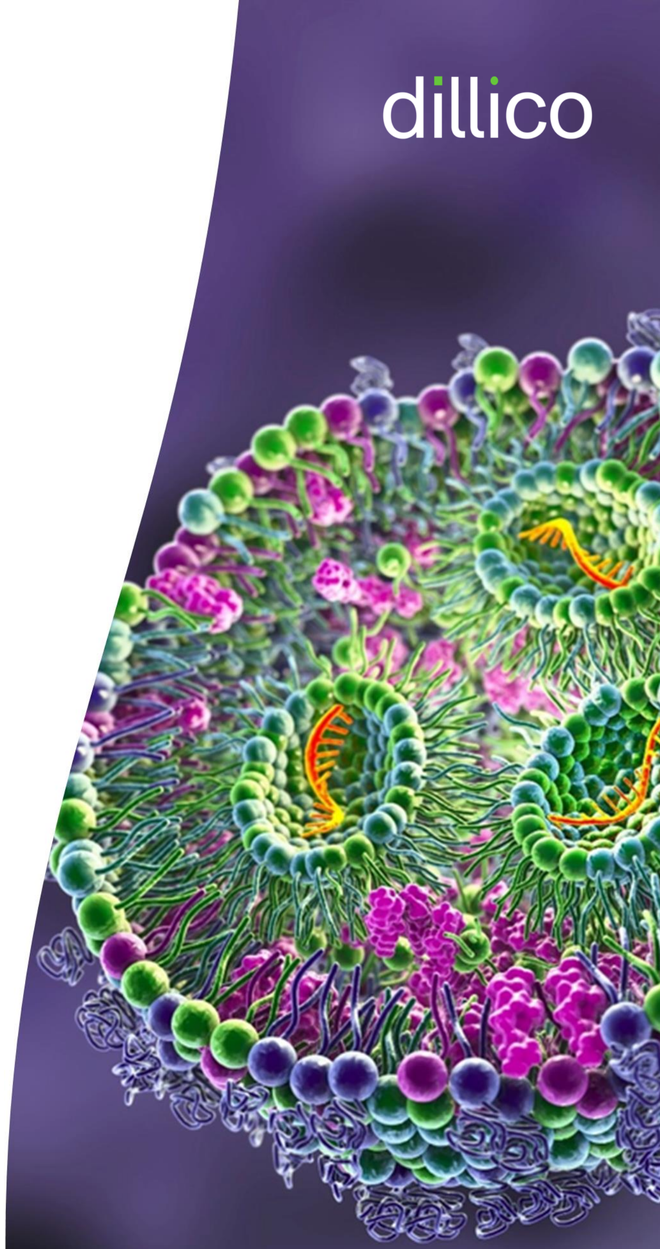
bpifrance

MIT researchers to lead a new center for continuous mRNA manufacturing

A pilot-scale system, enabled by an $82 million award from the FDA, aims to accelerate the development and production of mRNA technologies.

Zach Winn | MIT News Office
July 13, 2023

"One of our platforms that we were progressing before the pandemic was to go to continuous manufacturing. We had a development project to do that. But Covid came along, and that changed our approach. And now we're kind of I don't wanna say stuck in this in this Covid platform."
Aaron ALLEN, Moderna, Global Quality Director



The Co-Founder Team

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