GHERARDO BAUDO, PhD

mRNA-LNP FORMULATION • PROCESS DEVELOPMENT • CMC & GMP TRANSLATION

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PROFESSIONAL PROFILE

Senior Formulation Scientist with 6+ years in mRNA lipid nanoparticle and lipoplex development, focused on **moving RNA products from bench to GMP**. Currently lead **R&D-to-GMP scale-up of mRNA-LNP processes** (microfluidic mixing, TFF purification, fill-ready concentration) and support the **CMC and analytical package for IND-enabling work** in cancer immunotherapy. Hands-on in **analytical method development and qualification, SOP and GMP documentation, stability programs**, and **technology transfer** with lipid suppliers, QC/GMP and manufacturing teams. Earlier built nanoparticle and mRNA-engineered cell platforms at Houston Methodist. PhD in Materials Science and Engineering; **11 peer-reviewed publications**.

Looking for: Lead or Principal Scientist roles in LNP formulation, process development and CMC at an RNA therapeutics company, taking platforms from research to GMP manufacturing and the clinic.

TECHNICAL EXPERTISE

mRNA production. Plasmid amplification and purification, template preparation, in vitro transcription with co-transcriptional capping, poly(A) tailing, mRNA purification and quality control.

Delivery platforms. mRNA-LNPs, mRNA lipoplexes, liposomes, biomimetic nanoparticles and MSC/EV-based delivery; lipid composition, encapsulation and organ targeting.

Formulation & translation. Microfluidic LNP manufacturing, tangential flow filtration (TFF), process scale-up, cryopreservation, storage stability, GMP/CMC technology transfer.

GMP, QC/QA & regulatory. GMP documentation and SOP authoring, analytical method qualification, QC release-testing strategy, stability and requalification protocols, raw-material and lipid-supplier qualification, CMC input for IND submissions, GCP (FDA focus) and CITI trained.

Characterization & QC. DLS/zeta, NanoSight/NTA, NanoFCM, cryo-TEM, HPLC–ELSD; RiboGreen, NanoOrange and PicoGreen assays for mRNA, protein and dsDNA quantification.

Biological models. Mammalian, neuronal and stem cell culture; rodent dosing by IV (tail vein, retro-orbital), intraretinal, intranasal, intraperitoneal and intratracheal routes; biodistribution and preclinical efficacy studies.

PROFESSIONAL EXPERIENCE

Senior Formulation Scientist

Jan 2026 – Present

University of Florida | Department of Neurological Surgery, Sayour Lab | Gainesville, FL

- **Lead R&D-to-GMP scale-up of mRNA-LNP formulations for a planned clinical program.** Define scalable microfluidic production, TFF purification, concentration and fill-ready formulation; investigate and resolve particle-size growth during scale-up; establish critical quality attributes and in-process controls with QC/GMP and manufacturing partners.
- **Support CMC and analytical packages for IND-enabling work** on mRNA cancer immunotherapy products (LNP and lipoplex platforms): process descriptions, characterization data, stability plans and specifications for drug-product testing.
- **Develop, validate and qualify analytical methods for QC and stability:** HPLC–ELSD lipid quantification (DOTAP), RiboGreen mRNA assays (linearity, spike recovery, matrix effects), NanoOrange residual protein and PicoGreen residual dsDNA; NanoSight requalification.
- **Author SOPs and GMP-ready documentation;** work with lipid suppliers on raw-material quality and GMP-grade sourcing; train junior scientists in formulation and QC workflows.
- **Lead mRNA lipoplex vaccine formulation, cryopreservation and storage-stability studies,** optimizing complexation, particle size, aggregation and biological activity.
- **Design spleen-tropic mRNA-LNPs for in vivo CAR-T cell engineering** and contribute to 20+ multidisciplinary formulation collaborations in immunotherapy and vaccines.

Postdoctoral Fellow
Nov 2023 – Jan 2026

Houston Methodist Research Institute | Houston, TX

- **Engineered NRF1-mRNA LNPs for intranasal delivery in Alzheimer's disease.** Investigated brain biodistribution, neuronal delivery, neuroinflammation and mitochondrial function in 5xFAD mice.
- **Developed NRF1-mRNA-engineered MSCs and MSC-derived EV platforms for neuronal gene delivery.** Achieved ~35-fold NRF1 induction, ~50% higher ATP and reduced mitochondrial ROS in engineered MSCs.
- **Formulated and characterized mRNA-LNPs** (size, PDI, zeta potential, encapsulation efficiency, stability) and ran in vivo biodistribution and efficacy studies, writing protocols and reports for a funded translational program.
- **Studied NRF1-mediated mitochondrial rejuvenation and aging mechanisms,** linking mRNA-based cell engineering with neuronal protection, amyloid-β injury, apoptosis and neurite recovery.

Graduate and Visiting Research Fellow
2019 – 2023

Houston Methodist Research Institute | Houston, TX

- **Formulated 100+ dexamethasone-loaded liposomes for traumatic brain injury.** In vivo studies showed ~54% fewer apoptotic neurons and ~38% lower lesion volume.
- **Developed biomimetic nanocarriers for neuroinflammation and CNS delivery:** leukosome-based systems for inflammation targeting and neural-membrane-functionalized LNPs for neuron-targeted mRNA delivery (*Advanced Science*).

INSTRUMENTS AND SOFTWARE

- **Manufacturing & purification:** NanoAssemblr Ignite microfluidic mixing, uPULSE tangential flow filtration and cryopreservation workflows.
- **Analytical:** Agilent HPLC with ELSD (OpenLab), Zetasizer (DLS/zeta), NanoSight NTA, NanoFCM, plate-reader assays (RiboGreen, NanoOrange, PicoGreen), cryo-TEM.
- **Cell, in vivo & software:** BD FACSCanto II and Sony ID7000 flow cytometry, IVIS imaging, Seahorse, confocal microscopy; GraphPad Prism.

EDUCATION

PhD, Materials Science and Engineering | University of Chinese Academy of Sciences, Beijing | 2023

MSc, Biomedical Engineering | Polytechnic University of Turin, Italy | 2020

BSc, Mechanical Engineering | University of Florence, Italy | 2017

SELECTED PUBLICATIONS

2024 Baudo G, Flinn H, Holcomb M, Tiwari A, Soriano S, Taraballi F, Godin B, et al. Sex-dependent improvement in traumatic brain injury outcomes after liposomal delivery of dexamethasone in mice. *Bioeng Transl Med.*

2023 Baudo G, Wu S, Massaro M, Liu H, Lee H, Zhang A, Hamilton DJ, Blanco E. Polymer-functionalized mitochondrial transplantation to fibroblasts counteracts a pro-fibrotic phenotype. *Int J Mol Sci 24(13):10913.*

2023 Massaro M, Wu S, **Baudo G**, Liu H, Collum S, Lee H, et al. Lipid nanoparticle-mediated mRNA delivery in lung fibrosis. *Eur J Pharm Sci 183:106370.*

11 peer-reviewed articles and 1 preprint; 470+ citations, h-index 10 (Google Scholar).

AWARDS, GRANTS AND SERVICE

- **Awards:** 1st Place, Nanomedicine Symposium presentation award (2023); 1st Place, Three Minute Thesis (2022); ANSO Scholarship for Young Talents (2020). Co-author on five journal cover articles (2020–2025).
- **Grants:** contributed to the funded METAvivor Translational Research Award and NIH R56 (1R56EY036406-01A1, mitochondrial factories for macular degeneration), led by E. Blanco, Houston Methodist.
- **Service:** peer reviewer of manuscripts and preprints; poster judge, Italian Research Day in the World, Houston (2025); Treasurer, Comites Houston (2024–2025). Languages: English, Italian (fluent), Spanish.