

JULIA E SABLE

Summary

I am a dynamic research scientist and viral vector process development director with 22 years of experience in academic and pharmaceutical organizations. I command a diverse hands-on skill set that includes multiple formats of bioreactor platforms, primary and transformed tissue culture, scale-up and scale-down models, analytical assay development, Tech Transfer, SOPs, Process and GMP Batch record authoring, CRO/CDMO due diligence, Procurement specialist for cGMP and significant Project Management experience. I also have an extensive dossier of more than ten novel biology-based courses developed for Cooper Union, Rockefeller, Barnard and Columbia Universities and did my doctorate work in science education from Teachers College at Columbia University. I leverage and integrate my real world lab experience with my deep understanding of pedagogy to create courses that are both useful and engaging for undergraduates.

Highlights

Highly knowledgeable in cGMP mammalian tissue culture and upstream operations

including scalable bioreactor platforms (microcarrier, suspension, Ambr250 and fixed-bed iCellis and Univercells)

Upstream Technology Transfer internally including FMEA audits, IQOQ equipment validation, facility design for non-GMP and GMP spaces and externally with due diligence of CMOs and business development opportunities.

Platform to Pipeline Upstream Process Strategy including cell line development, GMP Master and Working Cell Banks and Viral seeds, robust QbD based n-1 tissue culture with static (ACFM) and bioreactors.

Strong working knowledge of **CMC guidelines** and technical writing experience for IND filings.

Experience

Associate Director, Viral Vector Development Legend Biotech, Piscataway, NJ

09/2020 to present

CMC Development of Upstream and Downstream process development, SOPs, Risk Assessment and Tech Transfer for scalable suspension based lentivirus production using Eppendorf BioBlu SU on 320 systems, novel and gentle clarification and ion exchange membrane chromatography technologies to maximize titer and percent recovery across processing.

Technical support for BCMA BLA filings in LVV and Analytical as well as providing tech support for multiple CDMO LV production in adherent and suspension platforms and submissions for pipeline IND filings.

Director, Pre-Clinical Vector Operations

05/2020 to 09/2020

Gene Therapy Program, U Penn, Philadelphia, PA

Lead for 12 person team of static derived AAV and lentiviral production for internal and external clients. Target production titers up to $1E+15$ gc for small and large animal studies. Yearly budget projections and liaison for project managers for IND filings.

Senior Scientist, Vaccine Process Development

09/2018 to 06/2020

Merck, West Point PA

Lead cross-functional development teams from PH2 oncolytic virus acquisition towards 2021 PH3 bulk campaign in Upstream Process development

Upstream Lead for Cells and Seeds: Leveraging QbD principles and extensive knowledge of mammalian tissue culture and virology, our team rapidly and robustly developed a new cell line for production of an oncolytic virus. My role was to oversee and produce a pre-master, master and working cell bank process, a master and working virus seed process, determine the final media formulation and scalable n-1 cell train process for large microcarrier bioreactor seeding to get to lock-in within one year for tech transfer to CMO for GMP manufacturing.

CRO Tech Transfer Lead for GMP Cells and Seeds Campaign included authoring detailed process descriptions, AA Testing SOPs and batch records for MCB, WCB, MVS and WVS campaigns. Cross trained CDMO for novel processes

Upstream Lead for iCellis Nano Bioreactors included head to head proof of concept OV production and bioreactor characterization with Applikon and mPath controllers. Solely responsible for equipment validation (IQOQ) and facility startup for connecting in bioreactor units to room utilities, performed investigations of process and equipment problems as needed and developed kappas. Using FMEA, developed a de novo fixed bed ELN template for capture of critical bioreactor readouts, metabolite and cell counter proxies. Generated monthly reports of potency and proxy data and a full COGs analysis for forecast expansion plan for manufacturing both at the PD scale and at the iCellis 500 large scale.

Partnered with Pall Biosciences as a first author to produce presentations for iCellis Super User Meeting (Amsterdam 2019) and posters at many virtual meetings (ASGCT, IGCT, etc.) to showcase technology advancements and novel PATs for fixed bed reactors.

Eppendorf 3L microcarrier, 50L and 250L SUBs. Cross trained the cells and seeds team to participate in all aspects of microcarrier process development and sample processing. Provided DOE and FMEA input to identify critical 3L and SUB reactor parameters. Provided upstream technical support and troubleshooting to attempt Ambr250 as scale down model for microcarrier.

Primary Upstream Process Lab Design for multiple team usage: Storage strategy for single use consumables, raw materials and freezer based inventory systems for sample logging and long term storage; room layout design to incorporate n-1 cell train equipment like mechanical and ACFM isolators for CCS40 manipulations as well as scale-down models of fixed-bed bioreactors and spinner cultures.

Primary safety lead and FDA inspection readiness coordinator to maintain a safe BSL2 working environment.

Interface with partner groups in analytics, downstream processing, formulation and manufacturing to ensure robust potency assays and a pathway to potential commercialization for fixed-bed and microcarrier bioreactor platforms. Established a high throughput imaging platform for identification of early viral infections via live cell dyes as proxies with both fixed and live cells in PET strips.

Procurement Lead for small and large scale bioreactor capital equipment, single use consumables, raw materials including inventory systems and management of critical supply chain related project timelines.

Merck talent recruiting representative for Columbia and UCSF. Attended focused talent recruitment meetings and maintained relationships with academic partner labs.

Director of Virology

05/2016- 09/2018

Columbia University, The Zuckerman Institute for Mind Brain and Behavior
New York, NY

Director of Virology for a state-of-the-art virus production facility that creates and supplies Adeno-Associated Virus (AAV), glycoprotein deleted CVS strain rabies, lenti and retro viruses as well as advanced molecular tool design including novel viral plasmids and CRISPR constructs.

Scientific:

Process Development and Analytical Optimization of established AAV and G-deleted N2C rabies virus for academic and commercial sales.

Development of novel plasmids and virus production for AAV and scAAV for clients.

Generation of novel self-inactivating G-deleted N2C rabies for functional and florescent tracing. Creation of SHRV G-deleted rabies for fish based neuronal tracing. Creation of self-inactivating N2CdG rabies system.

Financial:

Develop and maintain a complete not for profit business plan for production of a variety of molecular tools. Evaluate, purchase and maintain all capital equipment required for virus production and quality control.

Negotiate bulk purchasing for supplies required for virus production. Invoicing via iLabs and coordinate internal funds transfers for CU purchases.

Manage purchase orders (POs) and reconciliation of check payments from external and commercial labs. Reconciliation of lab P-card in ARC.

Yearly renewal of core licensing iLabs

Management:

Development of online inventories for molecular reagents (plasmids and virus stocks), capital and small equipment and all consumables.

Development and maintenance of virus production schedules. Training of employees in AAV and rabies production.

Developed and maintain material transfer agreements for academic and commercial labs with CU CTV office.

NeuroTechnology Center (NTC) Coordinator
Associate Research Scientist (Yuste Lab)
Columbia University, New York, NY

02/2014 to 05/2016

Scientific

Primary responsibility: Develop and maintain all optical setups including 2 Photon, 1-Photon spinning disk confocal, electrophysiology rigs and Spatial Light Modulator (SLM) holographic imaging systems.

Develop SOPs for mouse surgery/ husbandry, primary tissue culture and AAV virus production.

Provide laboratory safety training programs; Maintain IACUC, rDNA and HazMat protocols and liaison for ICM.

Financial

Manage an academic yearly projects budget of \$3.8M.

Maintain all lab financial reporting using ARC and FDS reporting systems.

Negotiate all purchasing for capital equipment, service contracts, and general lab supplies.

Grants: Served as the single point of contact for all aspects of grant submissions for Dr. Yuste, Yuste Lab Member Fellowships as well as all collaborative submissions to NIH, NSF, ARO, DARPA and IARPA.

NeuroTechnology Center Coordinator

Organizational: Planning and execution of yearly NTC Kavli Futures Symposium (<http://ntc-symposium.org/>) Development: Solely responsible for fundraising efforts from corporate and private donors that resulted in 50% of yearly operational budget.

Grant Writing: CU internal selection for the 2015 NSF Science Research Traineeship (NRT) to develop the NTC PhD educational curriculum.

Educational Outreach: WISC Girls Science Day; Dana Brain Awareness Week; Under the Lens Week at Hypothekids; Black Rock Forest Hydra Lab.

Social Media and Website Author: Developed and branded the NTC website (www.ntc.columbia.edu) as well as NTC Facebook and Twitter pages.

Lab Manager, Laboratory for Virology and Infectious Disease 07/2010 to 02/2014

The Rockefeller University
New York, NY

Scientific

Manage the laboratory infrastructure and day-to-day operations of a 60+ person, 4 PI research laboratory. Manager of Tissue Culture Core- oversaw production purchasing and QC to provide many transformed cell lines; primary hepatocytes and immune (CD34+) stem cells for humanized mouse models (HIS and HLC).

Developed one new large blood draw DENV protocol and maintained 6 existing IRB protocols. Develop and maintain IBC (rDNA) and NYS Tissue Bank protocols.

Manager of Virology Core- oversaw production and assay development and process optimization for viral potency including plaque, focus forming assays, relative infectivity (IF and luciferase based), TCID50 and high-throughput relative infectivity assays for HCV, DENV, CMV, lentivirus, adenovirus, influenza, AAV and many other BSL2 and 3 viruses.

Manager of BSL3 Viral Facility- implemented revised personnel training and SOPs. Maintained facilities for production of WNV, CKGN, non-human HCV and chimeric HCV.

Tissue and Viral Sample archiving for patient samples- managed collaborations with WCMC and MSSM tissue banks.

Operations

Facilities POC for 19 -80's, 3 Ultra/Cryo units, 24 Tissue culture incubators, 3 Acta HPLC. CBC - managed mouse colony of 1000+ cages.

RU-IT developed and maintained Bioinformatics (Galaxy) server and large data storage solutions.

Education/Outreach

Course organizer- Virology. Organized world-renowned virology speakers, archived course materials and lectures, managed graduate student seminars and exam assessment (journal article dissection and NIH grant panel format).

Instructor and Curriculum Developer for RU Science Outreach High School HCV Virology course.

Senior Research Associate (Sheetz Lab)
Departmental Confocal Core Manager
Columbia University, New York, NY

01/2000 to 07/2010

Scientific

Research Projects Description: Project 1: In vivo dynamics and quantification of PIP2 at the plasma membrane - cytoskeleton boundary and their effects on cell morphology and focal adhesion forces. Project 2: Mechano- differentiation of mouse or human iPSC lines without chemical intervention.

Relocated and Managed the laboratory infrastructure and day-to-day operations of a 30+ person research laboratory focused on cell biology and biophysics projects in the field of cellular motility and mechano-chemical sensing.

Procurement and design of advanced microscopy systems (Laser Tweezers, TIRF (with FRAP and TRAP), Olympus Confocal; Olympus Weather station for multi-day imaging)

Developed and standardized operation protocols (SOPs) for all standardized in vitro cell assays; coordinated equipment maintenance and repairs; maintained laboratory consumables.

Manager of tissue culture facility that provided transformed, primary fibroblasts and iPSCs for 4 PIs.

Developed novel Lentivirus process for STEMCCA to generate iPSCs

Financial

Manage an academic yearly projects budget of \$1.7M. Maintain all lab financial reporting to DA.

Negotiate all purchasing for capital equipment, service contracts, and general lab supplies.

Grants

Serve as the single point of contact for all aspects of grant submissions for Dr. Sheetz and Lab Member Fellowships as well as all collaborative submissions to NIH and NSF.

Obtained R01 funding for Project 1 for my research

Awarded 3 new RO1's and a PN2 NanoMedicine Center for Mechanical Biology from the NIH.

Departmental Core Imaging Confocal Facility Director.

Microscope Maintenance and training of 200+ person department for Olympus FV500 and FV300 systems.

Assistant Professor Adjunct (Biological Sciences)

09/2009 to 06/2010

Barnard College
New York City, NY

Development and implementation of BC1001 Biology for non-majors and BC 3002 Molecular Biology.

BC1001 is a large format, active learning conceptual-based introductory biology course for non-science majors. BC3002 is an intensive upper level molecular biology course designed to increase undergraduate scientific literacy through the use of primary literature in the fields of stem cells, epigenetics and bacterial antibiotic resistance.

Adjunct Professor Chemical Engineering

01/2006 to 06/2009

The Cooper Union for the Advancement of Science
New York City, NY

The Cooper Union for the Advancement of Science and Art, Spring 2006; Spring 2007: Fall 2008: Spring 2009. Development and implementation of new cell biology course, BIO 101 (Course was developed to attain AACSB accreditation)
Development and Implementation of new environmental biology and ecology course BIO 102 and Biochemistry course.

Both courses defined methods of study and critical concepts via profiles of historical and contemporary experiments (CREATE method with primary scientific literature).

Novel Assessment techniques: Pyramid Exam formats (students take MC exam once by themselves and again as a group with final grade a 75/25 percentage) Bottle Biology-ecosystems with weekly assessments.

Assistant Professor Adjunct (Biological Sciences)

01/2004 to 06/2008

Barnard College
New York, NY

Laboratory Instructor for BC BIO1001 and BIO2004 series. Facilitated weekly hands on science demos for biology major and non-major undergraduate courses. Prepared teacher demos, weekly assessments (quizzes and lab report grading) as well as set up and proctoring for cumulative practical exams.

The BIO1001 course encompasses the following content areas: structures and functions of plant and animal cells, reproduction and cell division, energy and food, general light microscopy. The BIO2004 course covers introductory biotechnology, DNA and recombinant bacteria, protein structure and analysis.

Faculty Instructor Frontiers of Science

06/2003 to 01/2005

Columbia College, Columbia University
New York, NY

Research Analyst I

09/1999 to 01/2000

Division of Hematology Duke University, Durham, NC

Scientific

(Dr. Marilyn Telen) Critical Factors in Basal Cell Adhesion Molecules/ Lutheran- Mediated Adhesion to Laminin. Created a baculoviral system to express soluble B-CAM/ Lu, Flow Chamber analysis of sickle cell patients to determine red cell adhesion mechanisms.

General lab manager duties and patient sample database organization.

Virus Vector Core Tech III

05/1999 to 09/1999

University of North Carolina
Chapel Hill, NC

(Dr. Jude Samulski) UNC Virology Core production of recombinant Adeno virus preps for gene therapy studies. Contract design and QC of Adeno based plasmids, RCA Assay and release potency assignment. Virus QC (titers) and production scale for rodent and canine studies.

Education

Doctorate of Philosophy, Science Education

Columbia University, New York NY

Master of Philosophy, Science Education
Columbia University, New York NY

Master of Science, Science Education
Columbia University, New York NY

Master of Science: Biology (Genetics)
Youngstown State University, Youngstown OH

Bachelor of Science: Biology
Youngstown State University, Youngstown, OH

Technical Skills and Areas of Expertise

Tissue Culture and Virology: Mammalian Tissue Culture of many transformed primary and stem cell lines including: immune cells, iPSC and ES lines, Transfections and Electroporation (BTX); Stable clone selection, multiple viral plaque assays, TCID50, replicon reporter assays, IF and IHC staining of live and fixed cells and mouse tissues, adenovirus and AAV gene therapy plasmid design, development of complete virus propagation of lenti and retro virus, glycoprotein deleted rabies systems (SADB19 and N2C and Self-inactivating delta G rabies), HCV, Flu, DENV, HAV, HBV, RSV, Measles, rVSVdG, Yellow Fever and several arboviruses.

Biochemistry: Protein Purification (His, Flag), HPLC, Ion Exchange Chromatography- Mono Q.

Mass Spec (ESI-MS and IC HPLC lipid analysis)

Molecular Biology Lab Techniques: Bradford, BCA All molecular biology basics (transformations, SDM, plasmid preps, etc.) Protein and DNA 2-D gel electrophoresis, SDS PAGE, Western Blotting.

FACS, multiple **luminometer platforms** (Omega, Berthold, Promega,); **qPCR** (Roche 480, Bio-Rad digital and QuantStudio 5-7), **ELISA**, and **Illumina NGS library preparation**.

Microscopy: Zeiss Optical Laser trapping (dual and single traps), TIRF (total internal reflection fluorescence) microscopy (Olympus), Confocal microscopy (Olympus), Fluorescent optical trapping (Olympus), FRAP, CALI, PALM, FRET and Cell Microinjection (Eppendorf), Sutter and Luigs Newman manipulators, 2 Photon (Prairie and home built), Spinning Disk Confocal (PE/Yokogawa), Spatial Light Modulators (SLM) by BNS and home built. Development of home-built STED microscope (Liao Lab), in vivo animal imaging with IVIS.

Mouse surgical techniques: generation of BLT mice, humanized liver chimeric mice, humanized immune system (HIS) mice, humanized erythropoietic mice (for DENV malaria studies), mouse census, breeding, IP and foot pad injections, retro-orbital bleeding.

Nanofabrication: plasma cleaners, PDMS nanoscale pillars, e-beam etch submicron patterning, Nano-imprint

Computer Skills

Complete Microsoft Office Suite (Windows, Excel, PPT, Project, OneNote and Outlook)

LabGuru (ELN) for mouse colony management, virus core lot documentation, inventory of virus stocks, equipment and protocols.

Statistics and Graph Software: Prism and Spotfire

Microsoft Image Analysis Software (ImageJ, NIH Image, Metamorph, FloView (Olympus), Nikon (Elements), Prairie, ScanImage 2015)

Image Editing Software (fully fluent Adobe Photoshop and Illustrator) Genetic Analysis Software (Snapgene, NCBI, GeneRunner) Bioinformatics Software (Galaxy)

Statistics Software (SPSS) Financial Software (ARC and FDS)

Grant Submission Software (eRA Commons; NIH PubSubmit; NSF Fastlane; grants.gov; IDEAS, ARO and DARPA Extranet)

Publications

Schwartzman M, Palma M, Sable J, Abramson J, Hu X, Sheetz MP, Wind SJ. "Nanolithographic control of the spatial organization of cellular adhesion receptors at the single-molecule level." *Nano Lett.* 2011 Mar 9;11(3):1306-12.

P. Timon McPhearson, Stuart P.D. Gill, Robert Pollack, and Julia E. Sable
"Increasing Scientific Literacy in Undergraduate Education:
A Case Study from "Frontiers of Science" at Columbia University"
Chapter 5: Knowledge Dialogue: Academic Institutional Governance, Education and Experiences (2010)

M. Schwartzman, K. Nguyen, M. Palma, J. Abramson, J. Sable, J. Hone, M.P. Sheetz, and S. J. Wind "Fabrication Of Nanoscale Bioarrays For The Study Of Cytoskeletal Protein Binding Interactions Using Nano-Imprint Lithography" *J. Vac. Sci. Technol.B*, 2009, 27, 61

Gallagher SS and Sable JE, Sheetz MP, Cornish VW.
An in vivo covalent TMP-tag based on proximity-induced reactivity.
ACS Chem Biol. 2009 Jul 17;4(7):547-56.PMID: 19492849

Sheetz MP, Sable JE, Doebereiner HG.
Adhesion of Cytoskeleton to Membranes Controls Membrane Domains
Annual Rev Biophys Biomol Struct. 2006;35:417-34.

Miller LW, Sable J, Goelet P, Sheetz MP, Cornish VW., Methotrexate conjugates: a molecular in vivo protein tag. *Angew Chem Int Ed Engl.* 2004 Mar 19;43(13):1672-5.

De Vos KJ, Sable J, Miller KE, Sheetz MP.

Expression of phosphatidylinositol (4,5) bisphosphate-specific pleckstrin homology domains alters direction but not the level of axonal transport of mitochondria.

Mol Biol Cell. 2003 Sep;14(9):3636-49. Epub 2003 Jul 11.

Niebuhr K, Giuriato S, Pedron T, Philpott DJ, Gaits F, Sable J, Sheetz MP, Parsot C, Sansonetti PJ, Payrastre B. Conversion of PtdIns(4,5)P(2) into PtdIns(5)P by the *S.flexneri* effector IpgD reorganizes host cell morphology. *EMBO J.* 2002 Oct 1;21(19):5069-78