

Nathan Giacalone

From: Susan Albright
Sent: Wednesday, April 6, 2022 9:45 AM
To: Nathan Giacalone
Cc: Amalia Timbers
Subject: docket item for Biosafety Committee
Attachments: Application-Jin Zhang.pdf

[DO NOT OPEN links/attachments unless you are sure the content is safe.]

Hi Nathan,
Would you docket this for me?

President Albright appointing Jin Zhang as a member of the Biosafety Committee

Include whatever else needs to be in the docket item. Attached is his resume - would you block out whatever is usually blocked out when you send a resume to the packet? I talked to him this morning and he is prepared to receive a phone call from you at some point asking about his availability to come to a meeting.

Thanks
Susan

Please find the contact information for Jin Zhang below...

[REDACTED]

[REDACTED]

[REDACTED]

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Susan Albright, President
Newton City Council
Councilor-at-Large Ward 2

Application Form

Profile

Jin _____ Zhang _____
 First Name Middle Initial Last Name

 Email Address

274 AUBURNDALE AVENUE _____
 Home Address Suite or Apt

AUBURNDALE _____ MA _____ 02466 _____
 City State Postal Code

What Ward do you live in?

Ward 4

 Primary Phone Alternate Phone

GSK _____ Sr. Manager _____
 Employer Job Title

Which Boards would you like to apply for?

Biosafety Committee: Submitted

Interests & Experiences

Please tell us about yourself and why you want to serve.

Why are you interested in serving on a board or commission?

I always had interest in government and this board would allow me to combine that interest with my career background to serve the public. I'm also interested because of the proposed development at Riverside that will include biotech labs and my home's proximity to that development.

 Upload a Resume

SUMMARY

Seasoned bench scientist and people manager with extensive biologic and gene therapy cell line development experience from the Research to CMC, including Module 3 BLA preparation, cell banking & testing, and LIVCA. Additional upstream process development experience such as Ambr15, process characterization, small scale bioreactor model, process tech transfer, deviation/CAPA handling, and risk assessment. Experienced with CDMO and external research partner collaboration including project coordination, meeting management, SOW preparation, and procure to pay. Hands-on experience with Operational Excellence/Lean methodologies, workshops, projects, and implementations. Trained in Sanofi Manufacturing System (Six Sigma Green Belt equivalent).

COMPETENCIES / SKILLS

Technical:

- Cell line development: DNA to stable cell bank for protein biologics and gene therapy vectors
- Upstream development: process characterization, process transfer, small scale model, process/facility fit assessment, master batch record preparation/review/approval, risk assessment, deviation and CAPA review/classification/approval
- CMC development: early stage: pre-candidate to cell bank release; late stage: late-stage development, IND/BLA preparation, LIVCA & monoclonality definitions, submission and inspection support
- Technology transfer of cell line development and analytical methods
- Analytical assay method development and qualification
- Molecular cloning, Southern/Northern/Western blots, copy number (qPCR and ddPCR), Crispr-Cas9
- ClonePix, CloneSelect Imager, CellMetric, single cell printer, BLI Beacon, Ambr15
- Flow cytometry (analytical and sorting), operated BD Calibur, FACSAria, Celesta, LSR II, FACSArray & Sartorius iQue
- Microsoft Office suite (Word/Excel/PowerPoint/Visio/Teams/Project/OneNote/Sharepoint), Veeva Vault, JMP, FACSDiva, FlowJo, CellQuest, VectorNTI, SnapGene, Sequencher, GeneData Bioprocess, Freezerworks, FreezerPro, Miro, LucidChart, SmartSheets

Business:

- Operational excellence/Lean: defining project, workshop facilitation, process mapping/analysis, implementation, capacity modeling, Lean training for organization
- Experienced in global multicultural environments (US, Europe, and Asia)
- CDMO, CRO, and partner management
- Business processes support (procure to pay, capex, opex, logistics)

Organizational:

- People manager, direct reports and indirect reports in matrixed organization; performance management; people development; on-&off-boarding
- Presentation at group, department and project meetings; presentation at multiple management-level (departmental to executive) meetings on technical, CMC, and operations matters
- Diverse project management experience within and across functions, and with external partners at multiple engagement levels from leading teams to individual contributor
- Experienced with strategic thinking and tactical execution; Change management

PROFESSIONAL EXPERIENCE

4/2021 – Present	Moderna	Sr. Manager Technical Development Ops	Manager: Peter Wojciechowski
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Responsibilities:

- As a member of Knowledge Management, conduct workshops and process mapping to facilitate understanding of knowledge/document flow from bench to regulatory submission, identify and affinitize gaps, and achieve consensus on improvement plan. Manage subteams to execute on improvement and implementation.
- Representing KM, support establishment of TechDev wide digital knowledge capture strategy including gathering VOC, establishing user requirements, and evaluation of external vendor capabilities.
- Additionally, supervised summer intern to establish an initial demonstration COGS model tool; supporting COGS process mapping to justify implementation of an optimized E2E COGS process and tool.

8/2020 – 3/2021	GSK	Sr. Manager Upstream Process Development	Manager: Mei Shao
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- As a member of the Strategic External Development group, coordinate and manage externalized biologics programs at multiple CDMOs. Act as SME for cell line development, cell banking, LIVCA, and biosafety testing.
- As part of Upstream team, manage upstream development, at-scale bioreactor runs, PPQ readiness, and PPQ for Covid-19 neutralizing mAb project with Wuxi and VIR Biologics: coordinated WCB manufacturing/specification setting/testing/release, established GSK internal spec for MCB and WCB, LIVCA strategy and testing; supported MBR update and EBR review/approval; supported process characterization and associated technical report review/approval; supported Upstream lead in process transfer to Samsung Biologics such as small scale model studies to de-risk process and facility changes.
- Preparation of relevant modules for marketing application and IND amendment for the Covid-19 program.
- Supported legacy program for biosafety assay deviation, risk assessment, and PAI.

5/2003 – 7/2020	Sanofi (formerly Genzyme) Framingham, MA	Sr. Scientist Cell Line Development	Manager: Christine DeMaria
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- Supervision of up to three direct reports in preclinical CHO cell line development for biologics. Supervision and execution of AAV producer cell lines for gene therapy.
- Function representation on CMC or DS teams.
- Preparation and review of relevant technical reports and project related documents; preparation of cell substrate and LIVCA subsections for IND/BLA; respond/triage health authority questions.
- SME for cell line development, genetic characterization, monoclonality, and LIVCA on cross-functional teams.
- Science project team lead for research collaboration with outside partner to gain transcriptomic and metabolomic understanding of CHO expression platform, and to development optimized polishing conditions for platform purification method.
- Project core team member and workstream leader for operational excellence projects to improve CLD capacity/capability and to streamline global biologics material logistics process.
- Lean awareness training for CMC organization. Staff hiring, training, and development.

Key contributions:

- Serum-free CHO host cell line development: developed initial electroporation method, tested candidate host cell lines, and developed initial drug selection method, completed GS-knock out using Crispr-Cas9.
- Implemented codon optimization, and NGS for DNA and RNA sequence verification into cell line development work process.

JIN ZHANG

#262-22
274 AUBURNDALE AVE. NEWTON, MA 02466

- Supervised and/or performed cell line generation for >30 pre-clinical programs spanning wide range of modalities such as mono/bi/tri specific mAb, Fc-fusion, nanoparticle, nanobody, and enzyme; including several cell lines for life-cycle management of current commercial products.
- Since 2015, responsible for AAV cell line development for pre-clinical programs to ensure adherence to internal ways of working; completed 5 AAV cell line development with 1 IND approval to date.
- Genetic characterization assay redevelopment, qualification, and technical transfer for five current commercial products to meet more stringent health authority requirements.
- Supported 4 IND and 5 BLA submissions since 2019; of these 2 BLAs deemed corporate KPIs and approved/pending (US, Japan, EU); of these 1 IND approved.
- Trained FACSCalibur and FACSARIA operator; cell sorting support for department.

9/2000 – 3/2003	Ariad Pharmaceuticals Cambridge, MA	Research Associate Biology Group	Manager: Joëlle Gaschet
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- Generation and characterization of retroviral (MMLV) production cell lines.
- Relevant molecular biology to generate expression vector and for genetic characterization.
- T-cell isolation from whole blood/buffy coat; T-cell stimulation/transduction.
- Flow cytometry and FACSCalibur operation.

2/1999 – 8/1999	Eisai Research Institute Andover, MA	Research Associate Contractor	Manager: Gabriel Berstein
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- Expression vector construction and generation of a GPCR expressing cell line for compound screening.
- Assist in cell-based compound screening and Tecan robot implementation.

EDUCATION

9/1999 – 9/2000	Brandeis University Waltham, MA	Master's Molecular and Cell Biology	PI: Ruibao Ren
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- Animal handling, tail vein injection, bone marrow isolation, flow cytometry, tissue culture, necropsy.
- Conduct research to further define the animal model of CML and the roles of GM-CSF and IL-3, thesis titled: *Bcr-Abl Induces CML-like Myeloproliferative Disorder with Expansion of By-Stander Myeloid Cells Independent of IL-3 and GM-CSF in Mice*

8/1995 – 12/1998	Brandeis University Waltham, MA	Bachelor's of Science Biology	Bachelor's of Art Biochemistry
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- Magna cum Laude.
- Undergraduate research on rad51 independent dsDNA break repair in *S.cerevisiae*, thesis titled: *Preference For Wild Type Double Strand Break Repair Pathway in a Sgs1, Rad51 Double Deletion Strain*

EMPLOYMENT AUTHORIZATION

NATURALIZED CITIZEN OF THE UNITED STATES OF AMERICA.