Bryan Wilkens Pharmaceuticals Industry Professional
bryan.a.wilkens@gmail.com | linkedin.com/in/bryanawilkens

SUMMARY

Skilled industry professional with years of experience in the GMP manufacturing sphere, including team leadership and product management. **Strong technical writing skills, including regulatory documents, SOPs, drug development reports and quality investigations**.

EDUCATION

Bachelor of Arts, Anthropology – *SUNY Stony Brook, 2011*
Nuclear Medicine – *Manhattan College, 2013*
Supplemental Courses

- Radiation Safety Officer, *Dade Moeller (NV5), 2019*
- Risk-Based Approach to CSV, 21 CFR 11 & FDA Compliance, *Compliance.world, 2021*
- Process Modeling, Analysis and Redesign, *Michigan State University, 2021*

SKILLS

- Technical writing
- Data analysis
- Quality mindset

TECHNICAL PROFICIENCIES

- MS Visio
- Adobe Creative Suite
- 1QEM
- ETQ

EXPERIENCE

PRODUCTION MANAGER, *RAYZEBIO, JUN 2023 – PRESENT*

- Developed production department from the ground up, including hiring, process design, and SOP/document authoring.
- Facilitated cross-functional validation activities, technology transfer, and equipment qualification for new manufacturing site.

MANAGER, RADIOPHARMACEUTICALS, *RAYZEBIO, MAY 2022 – JUN 2023*

- Supported clinical drug product development from Phase 1 to Phase 3 internally and in coordination with CDMO.
- Collaborated with Regulatory Department to draft and revise regulatory documents (IND, IMPD, etc.) and support clinical trial application submissions.
- Authored development reports for drug product research.
- Conducted data analysis on clinical batches produced, using findings to drive process improvements.

PRODUCTION MANAGER, *AAA/NOVARTIS, SEP 2021 – MAY 2022*

- Managed and led production team, including operator scheduling, hiring, and developing experienced personnel.
- Coordinated cross-functionally and globally to successfully launch Pluvicto, including participating in a pre-approval inspection by the FDA.
- Certified Quality Investigator through Novartis' Investigator Certification Program.
- Scheduled drug product manufacturing.
- Reviewed and approved batch records.
- Authored department SOPs and documents.
- Authorized User on site's Radioactive Materials License.

PRODUCTION SUPPORT LEAD, *AAA/NOVARTIS, APR 2020 – SEP 2021*

- Supervised production team, including scheduling and personnel training.
- Coordinated cross-functionally to support technology transfer and validation activities of a new drug product (Pluvicto) and expansion of the manufacturing site.
- Collaborated globally to successfully draft and implement an optimized Master Batch Record for existing drug product across multiple sites, leading to overall improvement in workflow and GDP.
- Participated in and supported periodic FDA inspection of the manufacturing site.

SENIOR PRODUCTION TECHNICIAN, *AAA/NOVARTIS, APR 2018 – APR 2020*

- Performed commercial & clinical drug product manufacturing while complying with cGMP, aseptic principles and required procedures.
- Coordinated and participated in technology transfer and validation activities for increased commercial batch size of Lutathera.
- To support expansion of the site, travelled to Italy to provide direct input for new manufacturing lines at the manufacturer's plant.

Martha Pavon

From: Matthew Hadden <mhadden@rayzebio.com>
Sent: Thursday, November 30, 2023 11:21 AM
To: Bryan Parker
Subject: [External_Sender] Bryan Wilkens CV: RayzeBio, Indianapolis, IN
Attachments: Bryan Wilkens Resume v9.pdf

Hey Bryan,

See attached CV for Bryan Wilkens. Sorry for the confusion!

Matt

Matthew Hadden | Director, Health Physics

RayzeBio
5850 W. 80th Street
Indianapolis, IN 46278
E: mhadden@rayzebio.com
C: 765.432.8990

Martha Pavon

From: Bryan Parker
Sent: Thursday, November 30, 2023 2:30 PM
To: Martha Pavon
Cc: Sandy Pavon; Tammy Tomczak
Subject: Please add AI to CN634539
Attachments: [External_Sender] Bryan Wilkens CV: RayzeBio, Indianapolis, IN; 634539 AI 665.pdf

Hey Martha,

Please add the attached Additional Info to CN634539 for RayzeBio, Inc. A 665 is also attached.

Let me know if you have any questions.

Thanks.
Bryan