

# United States Jobs Expertini®

## Director, Production

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Company: RayzeBio

Location: United States

Category: other-general

**Job Title:** Director, Production **Location:** Indianapolis **Background:** RayzeBio is a dynamic biotechnology company headquartered in San Diego, CA. Launched in late 2020 and recently acquired by Bristol Myers Squibb (BMS) as a wholly owned subsidiary, the company is focused on improving survival of people with cancer by harnessing the power of targeted radioisotopes. RayzeBio will operate as a standalone entity within the BMS organization, maintaining its biotech culture with the opportunity to leverage the best-in-class oncology capabilities of BMS. RayzeBio is developing innovative drugs against targets of solid tumors. The lead asset, RYZ101, is in Phase 3 testing for patients with gastroenteropancreatic neuroendocrine tumors (GEP-NETs), as well as earlier stage testing for patients with small cell lung cancer (SCLC) and breast cancer. Led by a successful and experienced entrepreneurial team, RayzeBio aims to be the global leader in radiopharmaceuticals.

**Summary:** The Director of Production will be responsible for oversight, development, and leadership of drug product and isotope production teams. The Director of Production will set vision and drive a culture of compliance and teamwork in a GMP radiopharmaceutical environment. The Director of Production will work with department managers to establish KPI's, training programs, and setting of clearly defined roles and responsibilities for department personnel. The Director of Production will work cross functionally to meet corporate objectives and implement systems related to the commercialization of RayzeBio's programs. The Director of Production will establish and manage teams of high performers to ensure a consistent and timely global supply chain is achieved.

**Job Responsibilities:** Essential duties and responsibilities include the following.

Other duties may be assigned. Provide in-plant leadership for management and production personnel. Oversee and conduct performance reviews and lead employee development programs. Ensure GMP compliance for clinical and commercial drug products and/or isotope production. Manage vendor contracts and relationships related to GMP production cleanrooms and related services. Establish and implement robust employee training and KPI programs within a radiopharmaceutical environment. As necessary, draft GMP documentation including but not limited to Batch Records, SOP's, forms, Deviations, CAPA's, Change Controls and reports. Drive investigations and preventative action plans to ensure on-time completion and GMP compliance. Support facility and production expansion plans in the US and abroad as necessary. Support validation activities related to hot cells and production cleanrooms. Ensure compliance with NRC, EH&S and US/EU GMP regulatory guidelines as required. Education and Experience BS/MS or PhD in scientific related field 10+ years of experience in Radiopharmaceutical or injectable GMP manufacturing environment. Skills and Qualification Highly motivated and organized professional with strong interpersonal and communication skills. Proven experience building and managing teams in a GMP environment. Excellent professional ethics, integrity, and ability to maintain confidential information.

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