

## **EXPERIENCED MICROBIOLOGIST *align with job application***

### **SUMMARY**

I am a microbiologist who helps manufacturing companies align and optimize processes so they can release product on time while operating in an audit ready state so they can reduce the frequency of OOSes and the number of audit observations thus saving time and money.

My expertise lays in TGA/FDA/EU regulated pharma manufacturing developed over 15 years working in microbiology testing laboratories. I possess strong knowledge and practical skills of viable environmental monitoring, sample processing, scheduling, bacteriology, validation, process auditing, conducting investigations and documentation, especially plain writing. While leading and training teams of 3-15, I ensured results were delivered in full and on time. I have solid technical writing skills and a wealth of industry knowledge.

### **ACCOMPLISHMENTS *trim to 4, do not repeat info retained in career***

- Documented and process mapped 20-30 laboratory and viable monitoring processes
- Validated 3 media fill trial incubators including all testing and paperwork
- Validated MAS100 Air sampler(s) and developed tracking package and relevant controlled documentation
- Revalidated (and updated) 8 autoclave loading patterns and associated documentation
- Lead investigator for over 100 non-compliances and deviations related to testing and monitoring
- Compared PIC/S Guide for Good Manufacturing Practice for Medicinal Products PE009-14 to v13
- Reviewed draft Standard AS 2243.1 Safety in Laboratories - planning and operational aspects and submitted feedback to the authority
- Produced and delivered "How to apply scientific principles to trouble shooting" presentation via webex
- Between 2016 and 2018, delivered training in locations such as Melbourne and Perth to groups of up to 10
- Introduced flammable liquids containers, introduced dust containment cabinet, developed a master document encompassing microbiological laboratory processes
- Created and delivered a 12 month training plan to team
- Wrote the equivalent of a quality manual for the microbiology department
- Investigated and redesigned Amphotericin antibiotic assay (disc > well)
- Controlled the Aseptic Process Simulation program for 15 filling rooms (2+ years)
- OH&S Representative for laboratory (3+ years)
- Scheduled the work for and lead teams of between 2 and 15 microbiologists (8+ years)
- Mechanical aptitude (relaxed car's clutch, timing belt, do my own bicycle servicing)

### **CAREER EXPERIENCE**

#### **Yeatman October 2012 to present Microbiology Communicator**

I deliver presentations and discuss industry relevant topics via my blog and YouTube to maintain my industry knowledge of microbiology & GxP thereby ensuring I have the education, training and experience to work competently in TGA regulated industries.

- Reviewed ISO 14644-1:2015 Cleanrooms and associated controlled environments, part 1 cf. 2002 version  
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- Reviewed of PIC'S Guide for Good Manufacturing Practice for Medicinal Products PE009-14 cf. version 13
- Review of Draft Standard AS 2243.1 Safety in Laboratories - planning and operational aspects
- Regular advice provided in LinkedIn groups related to pharmaceutical manufacture and testing
- Technical documentation draft and update
- Creation of YouTube channel to discuss science careers, present knowledge and to increase my exposure

**Kaspersky May 2014 to present**

### **Technical Support Engineer & Trainer**

My problem solving, critical thinking and customer service skills are used to administer IT systems and troubleshoot the operation and deployment of security software across a range of physical and virtual operating systems including Linux, Windows Server, VMWare and ESXi. My documentation and CAPA skills are a great asset during the trouble shooting process and allow me to keep customer satisfaction above the proscribed 85% KPI. I also test pre-release, beta and patched software and train others.

- Typically investigate and solve over 40 incidents a month
- Delivered training in locations such as Melbourne, Perth to groups of up to 10 students
- Produced and delivered "How to apply scientific principles to trouble shooting" presentation via webex
- Due to high performance (100% KPI), sent to Moscow for Christmas Party
- Seconded to Kuala Lumpur, Malaysia B2C/B2C support site 1 month. Customer satisfaction increased 50%
- Jan 2016 – Moved to an Enterprise level software support role when Consumer division went off shore

**Bristol-Myers Squibb / Sigma / Aspen Pharma 2006-2012 (role redundant)**

### **Microbiology Team Leader**

- Validated equipment, methods and processes – **Microbial Count Methods, antibiotic assay**
- Introduced and certified new equipment – **Dust extraction cabinet, flammable goods containers**
- Designed experiments – **Investigated and redesigned Amphotericin antibiotic assay (disc > well)**
- Improved documentation, processes and introduced new processes and managed change – **Introduced flammable liquids containers, introduced dust containment cabinet, developed a master document encompassing microbiological laboratory processes**
- Provided expert advice to other departments – **Autoclave Validation presentation, key member of Site Consolidation Project**
- Developed and delivered presentations – **Microbiology for Non Microbiologists**
- Lead and developed a team of 2-5 – **Brought quiet team member out of shell, mentored Product Complaints analyst**
- Removed of non-value added work – **paperwork duplication**
- Interviewed and employed new team members
- Reviewed need to compressed air sampling and successfully justified methodology
- Ran Microbiology media expiry date confirmation project.
- Created and delivered a 12 month training plan to team
- Developed and implemented succession plan, later role was deemed redundant.

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## **Mayne Pharma 2004-2006**

### **Quality Assurance Microbiologist**

- Conducted monthly housekeeping audits and ran adhoc process audits while conducting viable environmental monitoring
- Improved documentation, processes and introduced new processes and managed change – **Change Management for Novatek LIMS system, media fill incubators**
- Process mapped over 20 methods – **Key member of Novatek LIMS system implementation project**
- Controlled the Aseptic Process Simulation program for 15 filling rooms
- Validated equipment, methods and processes – **7x Media Fill Incubators, many bioburden methods, preservative efficacy methods**

## **Mayne Pharma 2002-2004**

### **Senior Microbiologist**

- Oversaw the training of and delegated the workload for a team of 12-15
- Reviewed, updated and harmonised over 100 laboratory documents as part of the **Documentation Effectiveness Project**.
- Lead over 50 OOS investigations and wrote reports and deviations
- Provided expert advice to other departments – **Seconded to IT Department when developing Microbiology Trends Access Database**
- Validated equipment, methods and processes – **8 Autoclave Loading Patterns**

## **Faulding / Mayne Pharma 1997-2002**

### **Microbiology Analyst**

- Documented, updated and reviewed over 100 documents – **Redraw of ~22 Room Monitoring Diagrams using Visio**
- Calibrated automatic pipettes every 3 months
- Performed LAL (endotoxin) testing – **5-30 WFI samples per day**
- Validated equipment, methods and processes and prepared all documentation – **Merck MAS 100, RCS Plus, Bioburden testing**
- Prepared media for viable environmental monitoring for entire lab – daily
- Ran multiple autoclave cycles – daily
- Conducted Viable Environmental Monitoring of sterile and non-sterile facilities including testing, bacteriology, mycology and temperature monitoring
- Conducted viable environmental monitoring of filling rooms ancillary areas. WFI, compressed air, cooling towers
- Schedule 8 (Drugs of Addiction) Approved person
- EH&S Representative
- Level 2 First Aid Officer

## **EDUCATION**

- Bachelor of Science – Microbiology / Immunology: Monash University
- BSZ404A Train Small Groups: Melbourne University
- Diploma of Commercial Arts – Visual Communication: CATC. Including DaVinci Graduation Award

## **TRAINING**

- Effective Customer Communication – provided by TMI/Tack International DiSC “Panther/Owl”
- Analytical Services Team "Back to Basics" - provided by Bridgeworks - DiSC “Panther”
- Leadership Great Leaders, Great Teams, Great Results Program. 3 day course by Franklin Covey
- Mapping Business Communications. 2 day technical writing course by Tactics
- Effective Supervisory Management. 12 week course (6hrs/week) by Leadership Management Australia
- Problem Solving & Decision Making. 3 day course by Kepner Tregoe
- Introduction to Project Management (PMBOK – 3rd Edition Aligned). In-house self-driven
- Certified Information Systems Auditor (CISA) - certificate
- Computer Hacking Forensic Investigator (CHFI) - certificate

## **FUN FACTS**

- Active at state level in competitive cycling and race director
- Regular learner of guitar and bass
- Have memorised the periodic table
- Reading Shakespeare in the original Klingon