# Our team



Peter Mauger DIRECTOR PRINCIPAL PROCESS ENGINEER



Fernando Diaz PRINCIPAL MECHANICAL ENGINEER



**Michael Pecar** PRINCIPAL PROCESS ENGINEER



ENGINEER



Anna Hardie SENIOR PROJECT



Himanshu Kakkad Rob Kube

SENIOR ELECTRICAL & SENIOR PROJECT AUTOMATION ENGINEER ENGINEER





MECHANICAL ENGINEER



Mark Winter SENIOR PROJECT MANAGER

Sam Cook

ENGINEER

SENIOR PROCESS



Andrew Hartley

DESIGN AND DRAFTING

MANAGER

Sophia Wang PROCESS ENGINEER



Aaron Smith PROCESS ENGINEER



Sam Rankin



Thomas Hazell GRADUATE MECHANICAL ENGINEER



Tom Loipersberger TECHNICAL DRAFTING ENGINEER



# Associations



International Society of Pharmaceutical Engineers (ISPE) ISPE is the world's largest not-for-profit association serving its Members by leading scientific, technical and regulatory advancement throughout the entire pharmaceutical lifecycle. https://ispe.org/



American Society of Mechanical Engineers (ASME) ASME promotes the art, science & practice of multidisciplinary engineering and allied sciences around the globe. https://www.asme.org/



Institution of Chemical Engineers (IChemE) IChemE exists to advance chemical engineering's contribution for the benefit of society and to support the development of chemical, biochemical and process engineering professionals. https://www.icheme.org/



#### Engineers Australia



The Australian Society of Cosmetic Chemists The Australian Society of Cosmetic Chemists is a professional scientific organisation that promotes the advancement of the theory and practice of the science and technology of cosmetics, toiletries and perfumery. https://ascc.com.au/about-ascc/

# Contact us

South Australia (08) 7100 1122 | adelaide@bright.com.au Victoria (03) 8400 4481 | melbourne@bright.com.au Queensland (07) 3703 1280 | brisbane@bright.com.au

Our engineers are available to provide services anywhere in Australia. Where travel is not possible or cost effective, the latest remote access technology is utilised to ensure successful project delivery, regardless of location.

### www.bright.com.au

Engineers Australia is the national forum for the advancement of engineering and the professional development of its members. https://www.engineersaustralia.org.au



Safety Quality Project Management **Risk Mitigation** Drafting

Design



ENGINEERING CONSULTANTS

# Bright **Engineering Consultants** Pharmaceuticals Profile

## Who we are

Bright Engineering Consultants is a multidisciplinary engineering consultancy firm specialising in the Biotech, Pharmaceutical, Nutraceutical, and Cosmetics industries.

We are a business-needs focused, dynamic and agile engineering consultancy firm with over 80 combined years of relevant experience in the Biotech, Pharmaceutical, Nutraceutical, and Cosmetics industries. We understand the regulatory needs behind cGMP compliant industries, as well as the expectations of our clients. We understand that adhesion to safety, good engineering practices (GEP) and Quality by Design are paramount when executing projects to ensure the safety of the end users that put their trust in your products.

We typically work alongside you as part of an in-house engineering department, but can also work independently, acting on your behalf, to provide a single point of responsibility for the required services or deliverables.

Our qualified team, with connections throughout the industries in which we specialise, work closely with our clients to ensure they receive safe, fit-for-purpose, robust and cost-effective solutions backed by engineering best practices and timely, consistent results.

We value experience and knowledge and invest in broadening the experience of our staff through formal training, industry events, and networking. We actively manage our skills matrix to ensure staff practise the skills they need regularly to ensure successful project execution, every time.

Our experience delivering projects for industries subjected to regulatory demands, such as those outlined by TGA, FDA, PIC/S, EP regulations and other relevant ISO standards, makes Bright the ideal partner for your next project.



# What we do

We specialise in clean manufacturing engineering solutions, applying best industry practices in line with local, international, or corporate regulations.

Our specialist team is highly experienced in delivering tailored projects for our clients, catering for their needs, budgets, timelines, and quality deliverables.

We work, with leading local and international firms in the Biotech, Pharmaceutical, Nutraceutical, and Cosmetics sectors. Our clients continue to partner with Bright for effective and compliant engineering solutions.

## Facility Design

We work in unison with you our client and can support projects of any size, including green- and brown-field projects. By using existing or forecasted manufacturing data, we can develop concept design documentation to support cost estimations, business case studies, and CAPEX submissions.

### Process Equipment

We have built solid professional relationships with a range of competent local and international equipment suppliers, who we engage on your behalf. At the same time, we are not affiliated with any particular suppliers, ensuring our technology selection and supplier recommendations are always in line with your best interests and expectations.

## Drafting

We provide the latest in 2D and 3D drafting, starting with 3D laser scanning and physical measurement, inserting OEM equipment models and parts, and designing functional layouts, product-, traffic-, work-, and air- flows through your facility. We communicate this to you using a combination of traditional large format scale drawings and easy-to-use A3 drawings, as well as the latest in virtual- and augmentedreality outputs. Because of this level of detail, we can also provide virtual fly-through video tours for advertising, client engagement, or to improve your Standard Operating Procedures. Using modern video conferencing, we can bring your team together from multiple sites and offices and walk through your new facility before it's built to improve engagement, conduct risk assessments, and minimise the risk of changes during construction.



#### Services

Our multidisciplined team of engineers and professional drafters will design and size the required services for your project. We will develop the required documentation packages for tender and installation, including project timeline and Scope of Works for each trade.

Services and equipment projects that we have delivered for our clients include:

- ISO-Grade cleanroom HVAC systems
- Compendial water systems RO, UF, PW, WFI
- Pure steam generation
- Autoclaves
- Lyophilisers and freeze-dryers
- Bioreactors and incubators
- Centrifuges
- Homogenisers
- Emulsifiers
- Filling lines
- Label and packaging lines
- Parts washers
- CIP systems
- Temperature control units
- Vacuum systems
- Processing vessels
- Gas liquefaction systems
- Liquid waste management systems
- Environmental Monitoring and Control Systems

### Clean Utilities

At Bright we understand the importance of efficient and reliable utilities. In the case of GMP clean utilities, this need is amplified as equipment failure or operation outside of validated parameters may have a direct impact on product quality. We understand that there are people at the end of the supply chain that trust your products are safe for them and their loved ones.

Our team is highly experienced in providing engineering solutions for our clients clean utilities requirements, providing support for engineering design, sizing, vendor selection, installation, commissioning, and system validation.

## Project Management

We can manage your project from concept through to validation. We use specialist software and our own in-house tools to monitor and report on time, cost, and quality. We communicate and coordinate with all relevant parties, from operators to management, government bodies and regulatory authorities, other designers, builders and trades, and follow applicable change control requirements.

#### Safety & Compliance

- Risk assessments
- Hazard and Operability Studies (HAZOP)
- Australian Standard audits (guarding, dangerous goods & many others)
- GMP, internal specification audits
- Change control management
- Contractor management (Permits, JSA/SWMS)

#### Engineering Design and Innovation

- Concept workshops / sprints
- Rapid prototype development
- Proof of Principle (PoP)
- Proof of Concept (PoC)
- Design and construction drawings

#### **Time & Process Management**

- Project timing, scheduling and reporting
- Work breakdown structures
- Installation and commissioning schedules
- Critical path identification

#### Cost

- Project budgeting, cost tracking and reporting
- Capital proposals, including payback modelling
- Tender documents, evaluation and contracts
- Work breakdown structures
- Equipment selection and sourcing

#### Quality

- User Requirement Specification (URS)
- Process functional descriptions
- Project scopes, individual scopes of work
- Equipment performance specifications
- Design Qualification (DQ)
- Factory Acceptance Testing (FAT)
- Site Acceptance Testing (SAT)
- Installation supervision and contractor management
- Commissioning and validation (IQ, OQ, PQ)
- Detailed and documented technical inspections (ITPs)
- Hit-list management

#### Verification

- Measurement and logging of most common parameters (temperature, pressure, humidity, dust particles, power/current, belt speed, rotational speeds, surface roughness, vibrations, and many more)
- Inspection and test plans

# Our process

Initial Contact Phone / Email / Web To contact us, visit bright.com.au/contact



Ongoing Support We will provide ongoing client support including information storage, troubleshooting, and further upgrades