

TGA GMP Forum 2021

The TGA have announced the third TGA GMP forum on the their [website](#). Dates have been confirmed for **Wednesday, 12 – Friday, 14 May 2021**. The Forum will be held as a virtual event due to the ongoing uncertainty as a result of the COVID-19 pandemic.

The free event will cover a range of informative topics within Manufacturing Quality Branch's (MQB) GMP portfolio including information on changes in GMP oversight as a result of COVID-19 as well as technical GMP subjects and insights.

Who Should attend?

The 2021 GMP forum is suited to:

- Pharmaceutical industry professionals employed in quality, production, compliance and/or regulatory roles
- Australian sponsors and manufacturers of prescription, over-the-counter and complementary medicines and Active Pharmaceutical Ingredients (API) and biologicals
- Regulatory consultants representing clients within the therapeutic goods industry.

Program

The TGA GMP Forum 2021 will have a strong focus on GMP oversight during the COVID-19 pandemic as well as technical GMP requirements. In addition to the main sessions, the event aims to provide opportunities to engage with small to medium enterprises (SMEs) through a number of discussion panels and interactive sessions. A range of TGA GMP SMEs with extensive industry, public sector and regulatory experience will be presenting and participating in discussions across the course of the program.

12 May

- ✚ Overview of GMP Regulatory Activities - 11:15 am-12:00 pm
- ✚ Inspection Reliance (GMP Clearance) - 12:45 pm-1:30 pm
- ✚ Virtual GMP Inspections: Current Feedback and Future Considerations - 1:45 pm-2:30 pm
- ✚ Interactive Workshop: The cleanroom requirements for Biologicals - 2:30 pm-3:00 pm
- ✚ Interactive Workshop: Code tables for GMP Clearance – How to avoid validation issues - 2:30 pm-3:00 pm

13 May

- ✚ GMP for Medicinal Products Version 14 - 10:00 am-10:45 am
- ✚ How To Improve your GMP Compliance - Listed Medicines - 11:00 am-11:45 am
- ✚ GMP Inspection Trends for Non-Sterile Registered Medicines (Including Medicinal Cannabis) - 12:45 pm-1:30 pm



- ✚ Dispelling GMP Myths of Human Blood Components, Human Tissues, Human Cell & Gene Therapies - 1:45 pm-2:30 pm
- ✚ Interactive Workshop: GMP Clearance Applications Common Deficiencies - 2:30 pm-3:00 pm
- ✚ Interactive Workshop: GMP Licence applications – Common Pitfalls - 2:30 pm-3:00 pm

14 May

- ✚ GMP Learning from Inspection Findings for Sterile Medicines - 10:00 am-11:00 am
- ✚ GMP for Investigational Medicinal Products - 11:15 am-12:00 pm
- ✚ GMP Compliance Signal Management - 12:45 pm-1:30 pm
- ✚ TGA GMP Leadership Team Roundtable Session - 1:40 pm-2:00 pm

Click [here](#) to register and to access details of the full program.

Any questions or comments for the TGA regarding the forum, can be directed to a central mailbox GMPForum@health.gov.au

Resources

- TGA website [Industry Forum on Good Manufacturing Practice \(GMP\) - TGA Virtual GMP Forum 2021](#)