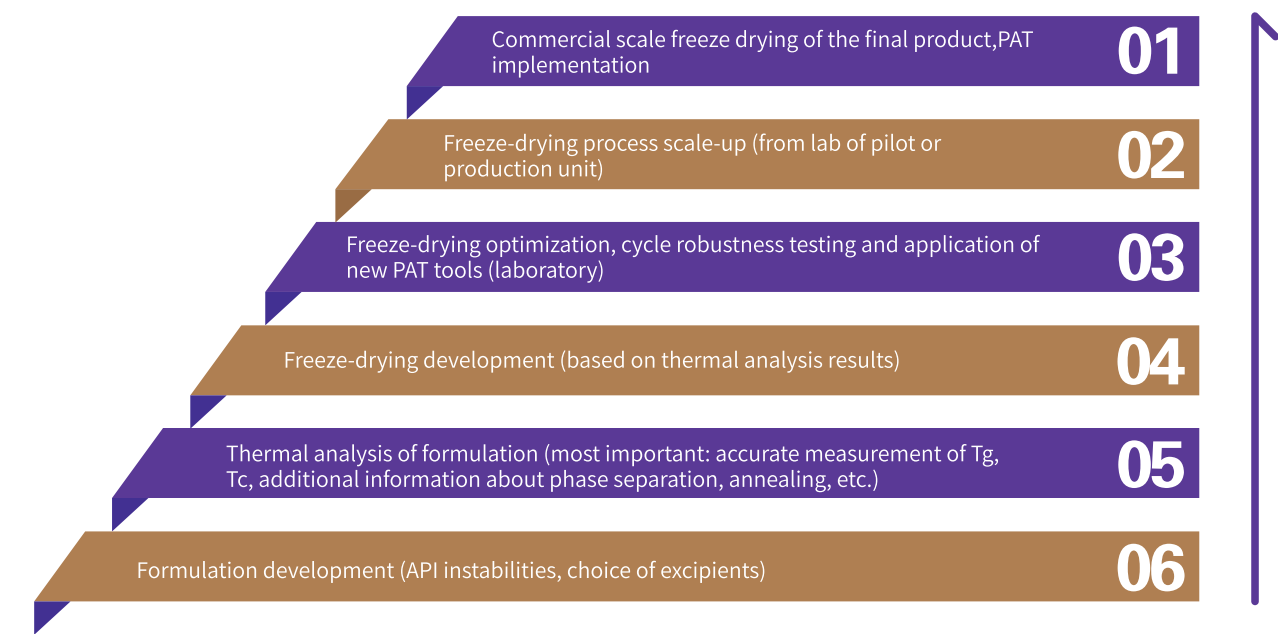
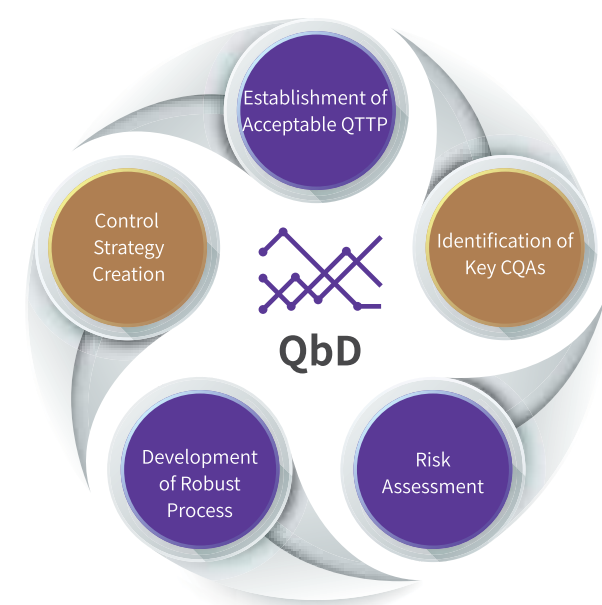


06 / SYSTEMATIC



07 / COMPLIANCE



All experimental processes, SOP, documentation, and summary report comply with the corresponding regulatory requirements, and the Compliance Consultation Business Unit of AUSTAR Group will help to meet the review requirements for the customer.

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Freeze-Drying Technology Solutions



Fill-finish

01 / LABORATORY OVERVIEW

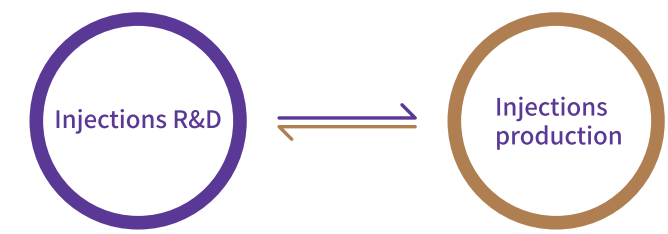
AUSTAR has established a professional freeze-drying laboratory who can assist pharmaceutical R&D and manufacturing companies to overcome the diverse challenges about freeze-drying application with the help of our advanced analytical instruments and experienced technical team.

The Service of AUSTAR Freeze-drying Laboratory



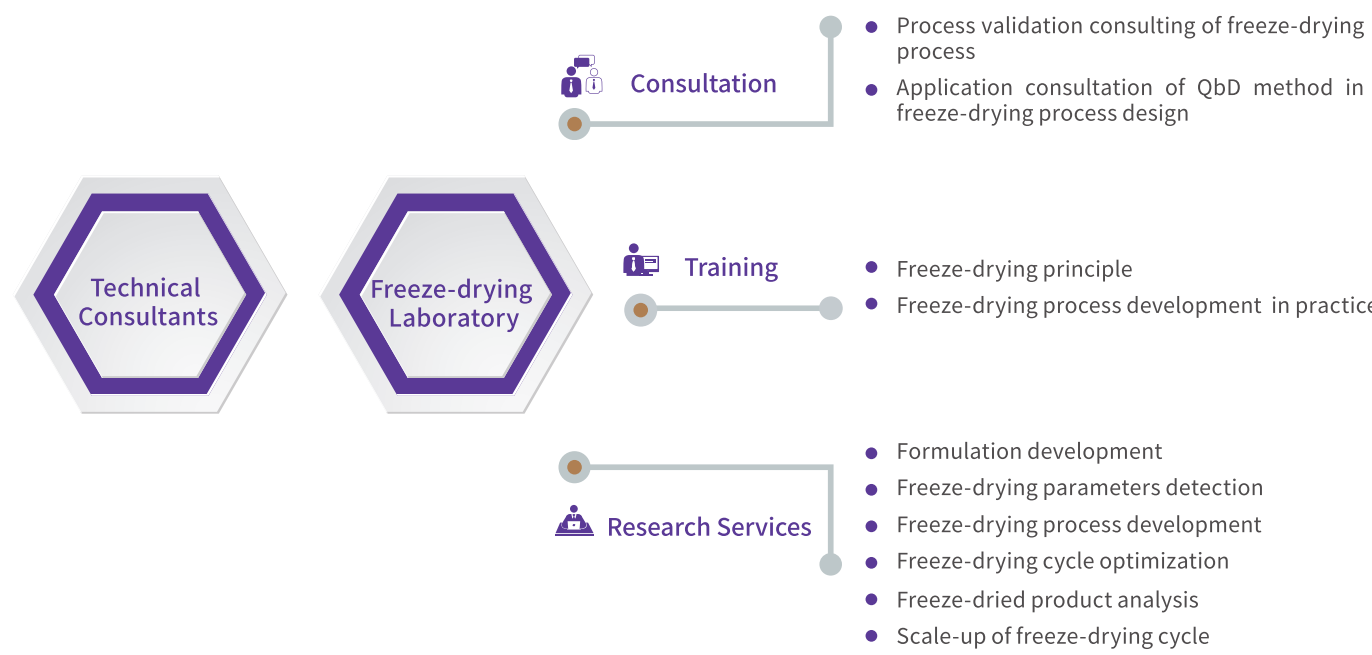
02 / ADVANTAGE INTRODUCTION

- ▶ We have advanced laboratory hardware, The laboratory is complete with MDSC, freeze-drying microscope, moisture tester, freeze-dryer, and other professional instruments. We have also established cooperation relationship with prestigious foreign universities, and through comprehensive analysis of the samples by using SEM, XPRD,μ-CT, etc.
- ▶ We have an expert consultant team, which includes Peter Haseley, the author of the book named Freeze-Drying, with decades of experience in freeze-drying, involving several categories of products: biological drugs, blood products, chemical drugs, cosmetics, foods and nutraceuticals, etc.
- ▶ We have a professional compliance consultant team and can provide the research services in compliance with regulatory requirements and QBD concepts.



- ▶ Process R&D under the guidance of QbD concept
- ▶ Key characteristics parameters of the drugs being measured by advanced instruments, which will be taken as the basis for determining process design space.
- ▶ Providing strong compliance support to pass drug review efficiently.
- ▶ Advanced process analytical technologies (PAT)
- ▶ The causes of the problem can be efficiently diagnosed and provide a systematic solutions with rely on the experienced technical consultant team.

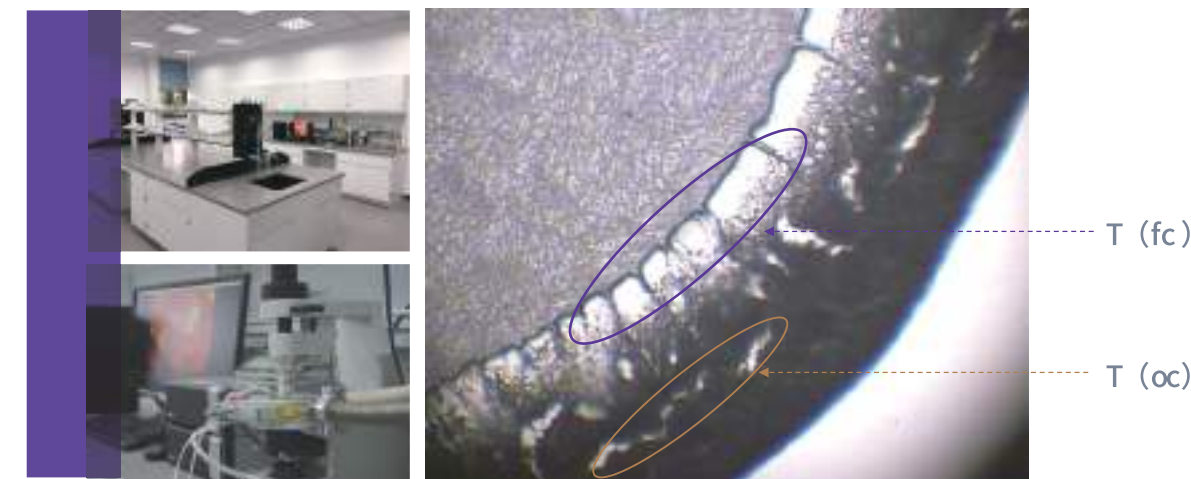
03 / SERVICE CONTENTS



04 / PROFESSIONAL INSTRUMENTS

FREEZE-DRYING MICROSCOPE

The freeze-drying microscope can rapidly simulate the freeze-drying process with a trace amount of samples, and the collapse temperature (Tc) can be observed and measured through a microscope. The collapse temperature is an important basis for the design and optimization of the freeze-drying process.



MDSC



FREEZE-DRYER



05 / EXPERT TECHNICAL CONSULTANT



PETER HASELEY has fifty years' experience in freeze-drying industry and wrote a book named Freeze-drying, which has been translated into Chinese. He has acted as an expert consultant in AUSTAR since 2008.