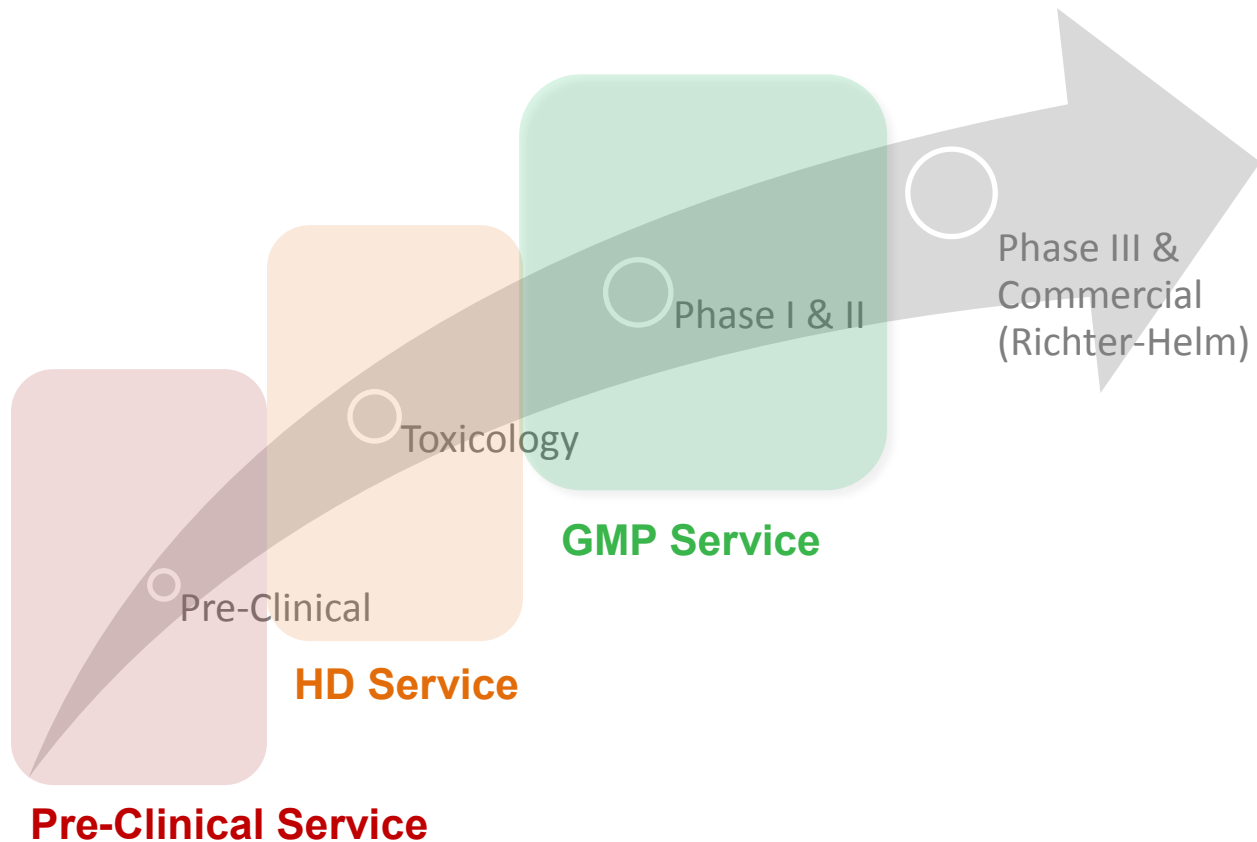


Highly Documented vs. GMP Plasmid Services

VGXI is a full service Contract Manufacturing Organization (CMO) providing Pre-Clinical through GMP plasmid DNA production. Highly Documented (HD) Plasmid Production is an intermediate service that may be ideal for some client projects. This service was specifically designed to provide plasmid DNA that will be used as a raw material in a GMP process, such as for GMP virus production. The HD service can also be used to provide plasmid DNA for use in pharmacology and toxicology studies.

For HD services, production is performed in the Process Development (PD) laboratory with a higher level of documentation than for standard Pre-Clinical production. The HD service provides a cost-effective solution for clients who do not require full GMP production for their project.

A detailed comparison chart of HD vs. GMP Plasmid Services is provided on the following pages.





Highly Documented vs. GMP Plasmid Services

		HD Cell Banking	GMP Cell Banking	Highly Documented Production	GMP Production	GMP Formulation and Fill
Production	Standard Yield	50 vials	200 vials	Based on VGXI capacity and client request	Varying scales from 1-20g based on PE data	2 to 10mL vials up to validated #
	Facility Produced	PD Lab	GMP Cell Bank Facility	PD Lab	GMP Small Scale or Production Plant	GMP Fill/Finish Suite
	Formal Training Program	No ①	Yes	No ①	Yes	Yes
	Project Description/ Approval	HD Project Specific Instructions	Campaign Specific Instructions	HD Project Specific Instructions	Campaign Specific Instructions	Campaign Specific Instructions
	Process Development/ Optimization	As required	As required	As required	As required	As required
	Released Raw Materials	No ③	Yes	No ③	Yes	Yes
	Equipment Calibration & PM	Yes	Yes	Yes	Yes	Yes
	Equipment Qualification/ Validation	No	Yes	No	Yes	Yes
	Equipment Cleaning Documentation	Research	QA Controlled	Research	QA Controlled	QA Controlled
	Equipment Cleaning	Yes	Yes	Yes	Yes	Yes
	Equipment Changeover	Per Client Request ②	Per Client Request ②	Per Client Request ②④	Yes	N/A ⑤
	Facility Cleaning Documentation	AM Controlled	QA Controlled	AM Controlled	QA Controlled	QA Controlled
	Documented Facility Cleaning	Yes	Yes	Yes	Yes	Yes
	Validated Facility Cleaning	No	Yes	No	Yes	Yes
	Manufacturing Documentation	AM Controlled	QA Controlled	AM Controlled	QA Controlled	QA Controlled
	Aseptic Bulk Filtration and/or Fill/Finish	N/A	N/A	Per Client Request ②	Yes	Yes
	Documented Deviations	Per Client Request ②	Yes	Per Client Request ②	Yes	Yes
	Area Doc Review	Yes	Yes	Yes	Yes	Yes
	Formal QA Doc Review	Yes	Yes	Yes	Yes	Yes
Material Storage Location/Requirements	PD Lab	QA Controlled	PD Lab	QA Controlled	QA Controlled	



Highly Documented vs. GMP Plasmid Services

		HD Cell Banking	GMP Cell Banking	Highly Documented Production	GMP Production	GMP Formulation and Fill
Quality Control	Environmental Monitoring	No	Yes	No	Yes	Yes
	Validated QC Testing ⑥	Yes	Yes	Yes	Yes	Yes
	QC Testing Documentation	HD ⑦	QA Controlled	HD ⑦	QA Controlled	QA Controlled
	In-Process Testing	QC	QC	QC	QC	QC
	QC In-Process Testing	Yes	Yes	Yes	Yes	Yes
	Pre-Approved Release Specs	Client provided/ approved	QA Controlled/ Client approved	Client provided/ approved	QA Controlled/ Client approved	QA Controlled/ Client approved
	Documented OOS	Per Client Request ②	Yes	Per Client Request ②	Yes	Yes
	Sterility/ Bioburden Testing	N/A	N/A	No ② Bioburden only	Yes	Yes
	Stability Protocol/ Testing	Per Client Request ②	Per Client Request ②	Per Client Request ②	Yes	Yes
	Area Doc Review	Yes	Yes	Yes	Yes	Yes
Formal QA Doc Review	Yes	Yes	Yes	Yes	Yes	
Quality Assurance	GMP Agreement	Per Client Request ②	Yes	Per Client Request ②	Yes	Yes
	Client Audit	Max 1 day – Quality System Review	Max 2 day	Max 1 day – Quality System Review	Max 2 day	Max 2 day
	Certificate of Analysis	HD C of A	Yes	HD C of A	Yes	Yes
	Product Dispositioned	Yes	Yes	Yes	Yes	Yes
	Documentation Provided to Client	HD Batch Record	QA Controlled Batch Record	HD Batch Record	QA Controlled Batch Record	QA Controlled Batch Record

- ① GMP and job skill training documented. Procedure training documented where required.
- ② Client requested items will affect project pricing
- ③ Utilizes same catalog #s as GMP Production
- ④ HD changeover testing is TOC only
- ⑤ All product contact equipment/parts are single use
- ⑥ For standard QC assays
- ⑦ Utilizing same QC test methods
- ⑧ Research C of A may be issued for Research Cell Banks that will be utilized in GMP Cell Bank production