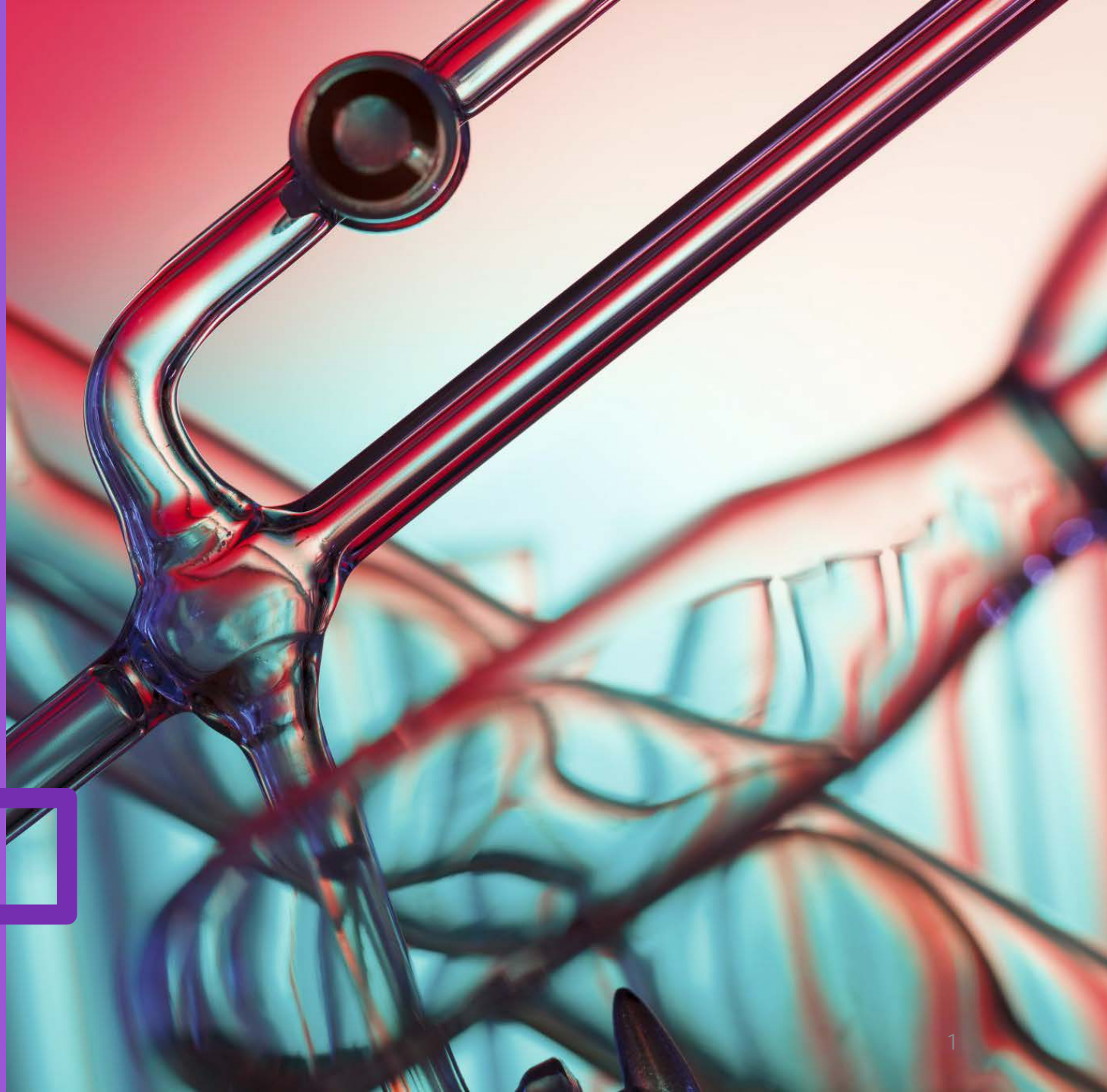


Guidance on Purchasing Gene Synthesis Equipment or Products

in Compliance with
● AB 1963
Guidance Memo 23-02

04/26/23





Overview

- **Welcome** (audience: UC, CSU)
- **Chat** for questions
- **Timing** Presentation (15 min) | Q&A (5 min)
- **Questions** (CSU available at the end)



Purpose

WEBINAR GOALS

- Provide an overview of AB 1963 and Guidance Memo 23-02 developed in response to AB 1963
- Share resources to help with compliance

SPEAKER INTRODUCTION

- **Agnes Balla**
UCOP Director of Research Policy Analysis and Coordination
- **Sheryl Major**
UCSD Biosafety Officer
- **Philip Barruel**
UCD Biosafety Officer
- **Laurence Kruger**
UCOP Manager, Unified Instance | Commerce

Background



AB 1963

- Governor signed **AB 1963** into law in **August 2022**
- Requires CSU and requests UC to “develop systemwide guidance for purchasing gene synthesis equipment or gene synthesis products from providers who prevent the misuse of synthetic genes and safeguard the benefits of gene synthesis technology while minimizing risk.”

Gene Synthesis Provider

What is a “gene synthesis provider”?

- **“Gene synthesis provider”** means an entity that does any of the following:
 - (A) An entity that creates gene synthesis products for delivery to a customer.
 - (B) A distributor of gene synthesis products, including, but not limited to, entities who manufacture gene synthesis products for use by other parties, both inside and outside of the entity.
 - (C) A third-party entity that is not the end user of a gene synthesis product and does not make gene synthesis products, but otherwise fills, completes, modifies, or purifies gene synthesis products.
- “Gene synthesis provider” does not include a research scientist making gene synthesis products for the research scientist’s own use or for use by another research scientist or an entity that manufactures gene synthesis products for the entity’s own use.

Guidance



UC Guidance Memo 23-02

- Ensure that gene synthesis provider meets the **International Gene Synthesis Consortium (IGSC) criteria** or that provider applies protections commensurate to the IGSC criteria
- Must happen **prior to purchasing** gene synthesis equipment or products
- Applies to researchers, lab managers, students, and local procurement offices



IGSC criteria

Harmonized Screening Protocol for Gene Sequence & Customer Screening to promote biosecurity

<https://genesynthesisconsortium.org/wp-content/uploads/IGSCHarmonizedProtocol11-21-17.pdf>

Gene **sequence**
screening

Gene **customer**
screening

Record keeping

Order refusal &
reporting

Regulatory
compliance

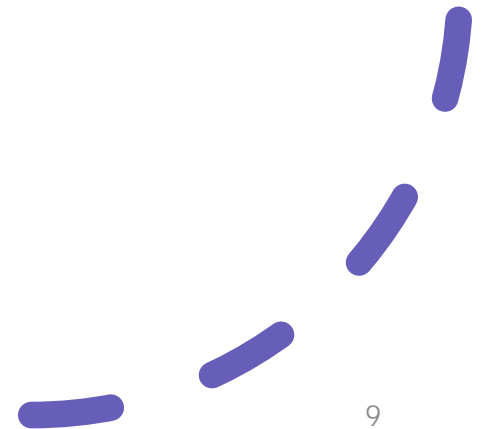
Commensurate
protections

- HHS Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA
 - Screen customers and product
 - “Sequence of concern”

Actions

Resources for Compliance

- Review the **guidance document**
- Use the **Smartsheet tool**
- Or providers may complete a paper **Attestation form** (Appendix I)
- Check **Smartsheet tool** prior to purchasing system



Procurement

SmartSheet demo

🕒 **AB-1963 Gene Synthesis Suppliers** ☆



&



[Request a new supplier completes the AB-1963 Attestation Form](#)

You will be notified when the supplier submits a response.

[Request multiple suppliers be contacted](#)

Please copy and paste the suppliers into the following site to request multiple suppliers be contacted

AB-1963 Gene Synthesis Suppliers

Supplier Name	Status	Follows IGSC Protocol	Applies Commensurate Protocols	Contact First Name	Contact Last Name	Contact Email	Date Sent	Date Signed
10X GENOMICS INC	Requested	<input type="checkbox"/>	<input type="checkbox"/>	Lindsay	Fletcher	lindsey.fletcher@10xgenomics.com	04/14/23	
Azenta - GENEWIZ INC (possible)	Requested	<input type="checkbox"/>	<input type="checkbox"/>	Casey	DeCesari	Casey.DeCesari@azenta.com	04/14/23	
BGI AMERICAS CORP (china hq)	Requested	<input type="checkbox"/>	<input type="checkbox"/>	Hongyan	An	hongyan.an@bgi.com	04/14/23	
BIO RAD LABORATORIES INC	Requested	<input type="checkbox"/>	<input type="checkbox"/>	Chris	Lee	Chris_Lee@bio-rad.com	04/14/23	
Bioneer	Received	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Edgar	Elenes	Edgar.elenes@bioneer.us.com	04/14/23	04/17/23
Bon-Opus Biosciences	Requested	<input type="checkbox"/>	<input type="checkbox"/>	Tai-Yun	Kuo	tai-yun.kuo@bonopusbio.com	04/14/23	
Complete Genomics (sub of MGI)	Requested	<input type="checkbox"/>	<input type="checkbox"/>	Anissa	Baxter	abaxter@completegenomics.com	04/14/23	
Element Bio (new)	Requested	<input type="checkbox"/>	<input type="checkbox"/>	Shelley	Peariso	shelley.peariso@elembio.com	04/14/23	
EUROFINS GENOMICS LLC [Op]	Received	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Jessica	Rhine	bhbcs@blueheronbio.com	04/14/23	04/17/23
Genscript Biotech	Requested	<input type="checkbox"/>	<input type="checkbox"/>	Yasmine	Shakibi	yasmine.Shakibi@genscript.com	04/14/23	
ILLUMINA INC	Requested	<input type="checkbox"/>	<input type="checkbox"/>	Rachel	Spetzger	rspetzger@illumina.com	04/14/23	
INTEGRATED DNA TECHNOLOGI	Requested	<input type="checkbox"/>	<input type="checkbox"/>	Daniela	Marosi	djmarosi@idtdna.com	04/14/23	
LGC BIOSEARCH TECHNOLOGIE	Requested	<input type="checkbox"/>	<input type="checkbox"/>	Emily	Sether	Emily.Sether@LGCGroup.com	04/14/23	

Health & Safety

- Ensure suppliers verify that **procurement** requirements are being met
- Obtain other **approvals for biosafety and biosecurity** (e.g., IBC, DURC, etc.)

Questions

