



ISPE

**GREATER
LOS ANGELES
CHAPTER**

**26th Annual
Vendor Night**

May 9, 2019

at the Iconic

Globe Theatre

in DTLA

(DownTown Los Angeles)

<http://atdevents.net/register.php>



La La Land

Welcome to the place where magic happens

Since the early 1900's, Los Angeles has been the hub for movie production.

This year we are celebrating this rich movie heritage and inviting you to join us for a fun networking event in this iconic building,

the Globe Theatre

740 South Broadway, Los Angeles CA 90014

Three floors of Fun!

Join us on May 9 in DTLA!

New Format At This Year's Event

This year's Vendor Night will begin with four Tech Talks from 2-4pm in the lower level of the **Globe Theatre**.

The exhibit show opens at 4pm with a Keynote Presentation by Michael de la Torre, the CEO of Govzilla & FDAzilla on the main stage.

Following the Keynote, the networking begins. Throughout the evening new product and services will be presented on the main stage.

Jennios Onsite Taco Bars will be serving up delicious tacos during the evening.

Join us on May 9 in DTLA!

Keynote Presentation

Michael de la Torre
CEO, Govzilla and FDAzilla

26th Annual ISPE Los Angeles Vendor Night

May 9, 2019

4:00PM

Mainstage

Trends in Production Systems and Facilities and Equipment

Pharma 4.0

Data Integrity and Continued Process Verification (CPV)
Using FDA 483s As A Source of Data for Analysis

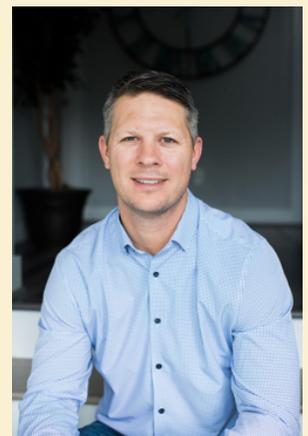
In this data driven generation, how do we identify, prioritize, and address engineering challenges? We will be exploring FDA inspections, Warning Letters, CFR citations, and 483s with a particular focus on engineering challenges, like Facilities, Equipment, and Data Integrity pertaining to computerized systems. We leverage our unique data set of over 70,000 parsed 483 Observations and apply Machine Learning tools to categorize these Observations and make meaning of the FDA's evolving focus. We cut the data and parse the issues by FDA Center (eg CDER) and Region (eg Asia).

About the Speaker

Michael de la Torre, CEO, Govzilla and FDAzilla

Michael has been an executive at multiple software start-ups and manufacturing companies in the Bay Area and Utah. Prior to that, he was an Associate at Oak Tree Capital. Previously, he was a Consultant at McKinsey & Company with a primary focus on energy clients including utilities and integrated majors.

Mr. de la Torre has a BA in International Finance from Texas A&M University and an MBA from The University of Chicago Booth School of Business, where he received the Outstanding Student Award for having the highest GPA in his graduating class. He currently resides in Pleasanton, CA with his wife and three sons.



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Schedule	Event/Location	Details
Noon - 2:00PM	Exhibitor Set Up All Floors	See Exhibitor Guidelines and Information page in this document for more information
2:00 - 4:00PM	TECH TALKS Lower Level	Multi-Part Session to Help Increase Your Knowledge and Increase Your Value
4:00PM	Exhibit Show Opens with Keynote Presentation Main Stage	Trends in Production Systems and Facilities and Equipment Michael de la Torre CEO Govzilla and FDAzilla
4:00 - 8:00PM	Exhibit Show All Floors	Free to Attend Must be 21 or older
5:00 - 6:00PM	Student Posters Lower Level	Chance to Interact with Student Presenters
5:00 - 7:30PM	New Product and Services Presentations Main Stage	
8:00PM	Show Ends Exhibitor Tear Down	See you next year!

Thank You To Our Chapter Sponsors

PLATINUM



PSC Biotech



GOLD



SILVER



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Exhibitor List and Table Number		Exhibitor List and Table Number	
Astropak	PR 5	ISO-MED Inc.	R 20
Automated Engineering Services	PR59	Kinetics	PR 22
Banks Integration Group	PR 7	Lives International	PR 20
Bausch + Stroebel Machine Co.	PR 42	MarkLogic	PR 15
Burkert Fluid Control Systems	PR 45	MD Stainless Services Inc	PR 8
CAI	PR 1	Measurement Science Conference	PR 11
CAI	PR 2	Murray Company	R 5
California Electrical Services	PR 52	Nora Systems Inc	PR 19
Camfil	PR 24	Pacific Coast Contracting	R 4
Cannon Building	PR 46	Pacific Rim Mechanical	PR 40
CDG Builders, Inc.	R 22	PSC Biotech Corporation	PR 3
Cleanseal Door Systems	PR 39	R2A Architecture	R 14
CRB	PR 30	Rommelag Flex	PR 54
Dome Construction Corporation	PR 18	ROTRONIC Instrument Corp.	R 21
DPR Construction	PR 21	RoviSys	PR 47
Duhig Stainless	PR 58	Royal Welding & Fabricating	R 19
EHS Solutions LLC	PR 32	Rudolph & Sletten	PR 9
Eichleay, Inc.	PR 31	Semitorr Group	R 10
Ellab, Inc.	PR 14	Servolift	PR 28
Evoqua Water Technologies	R 16	Siemens - Smart Infrastructure	PR 36
EwingCole	PR 26	Siemens - Smart Infrastructure	PR 37
FDazilla	PR 49	Siemens - Smart Infrastructure	PR 38
Feldmeier Equipment, Inc.	PR 44	Statco-DSI	PR 41
GL Planning & Design	PR 17	Steris Corporation	R 3
Hamilton Company	PR 13	Suez WTS Analytical Instruments	PR 53
IMA Life North America	R 2	Technical Safety Services, LLC	PR 55
IPS	PR 56	Trinity Process Solutions Inc	PR 6
ISEC	PR 4		

Increase Your Knowledge, Increase Your Value

Join Us for These

TECH TALKS

26th Annual ISPE Los Angeles Vendor Night

May 9, 2019

2:00-4:00PM

Lower Level

Pharma 4.0, Artificial Intelligence, and Big Data Looking to the Future of Pharma and Biotech

Bikash Chatterjee, President and Chief Science Officer, Pharmatech Associates

Beyond the ever-present need for pharmaceutical manufacturers to remain competitive in a growing marketplace of escalating complexity as regulators' push for continuous product monitoring. Why 4.0?

- The idea that the Industrial Revolution, characterized by mechanization and steam power, was: Industry 1.0
- The arrival of electricity was Industry 2.0
- The Internet was Industry 3.0
- We are now in the infancy of Industry 4.0 (and Pharma 4.0)



Pharma 4.0 represents Industry 4.0 concepts in the pharmaceutical setting. Industry 4.0 fosters what has been called a "smart factory". Within modular structured smart factories, cyber-physical systems monitor physical processes, create a virtual copy of the physical world and make decentralized decisions. Over the Internet of Things, cyber-physical systems communicate and cooperate with each other and with humans in real-time both internally and across organizational services offered and used by participants of the overall value chain. This presentation will explore how industry is approaching this objective through strategic deployment of IoT, Artificial Intelligence and Deep Learning solutions, and the application of Big Data Analytics across the drug development and commercial lifecycle.

Pharma 4.0: Innovation For Tomorrow With Next-Gen Technology Today

Bill Fox, JD, MA, VP Vertical Strategy Group, CSO Healthcare and Life Sciences, MarkLogic

Industry 4.0 is driving leading companies like Amgen and Chevron to build 360 views of their data—connecting data from across business silos including the supply chain - to improve efficiency, cut costs and simplify compliance.

In this discussion, attendees will learn how operational data hub technology is enabling pharmaceutical organizations to effectively:

- Transform data processes that typically take months into automated processes that take minutes
- Close the gap between the operational and analytical needs of life sciences companies
- Integrate enterprise data, whether R&D, pharmacovigilance, or supply chain, at a fraction of the time and expense of traditional technologies



Use of Semantic Technologies to Join Dissimilar Data and Provide Management with Performance Metrics

Alice Augustine, PhD, Information Scientist, Taxonomy Management Lead, Amgen

A practical innovative deployment of data analytics to improve Lane Management and Logistics will be presented along with how to overcome challenges in connecting data due to multiple data structures, inconsistent terminology, descriptions and internal systems gaps to facilitate meaningful analytics. An interesting design pattern relating to fact extraction from unstructured content and joining with structured data has enabled re-use of stagnant data locked in documents for meaningful analytics.



Using AI and NLP Tools to Trend Non-Conformances

Mark DiMartino – Quality Data Sciences Director, Amgen

- Deviation trending is a regulatory requirement with a primary goal of identifying recurring events.
- Effective deviation trending historically is labor intensive and has been difficult to efficiently and reliably implement.
- AI techniques such as Natural Language Processing and Machine Learning provide an opportunity to "automate" the identification of recurring deviations.
- Effective implementation of NLP requires well thought out terminology management.
- Successful implementation of an AI based trending tool requires a collaboration of data science, IS, and subject matter expertise to be successful.



About The Speakers

Bikash Chatterjee, President and Chief Science Officer, Pharmatech Associates

Bikash has over 30 years of experience in the design and development of pharmaceutical, biotechnology, medical device and IVD products. He has successfully achieved approval and commercialized over a dozen products in his career. Bikash has held senior management positions in several firms throughout his career prior to joining Pharmatech. He is a certified Lead Assessor and Lean Six Sigma Master Black Belt and is a frequent speaker at conferences around the world.

He is a member of the USP National Advisory Committee for API's and Excipients, LSIT Technical Advisory Board and The Stem Cell Partnering Advisory Board. Bikash currently provides recurring editorials to both Pharmaceutical Manufacturing and Controlled Environments magazine as an industry thought leader and is a member of their editorial advisory board. He is also a member of cPHI's Expert Industry Panel. He is also a member of the independent oversight group the RFID Alliance with specific expertise in the effective application of security and RFID in the pharmaceutical supply chain. He has designed and built biotech facilities on three continents and has established global supply chain frameworks for both large and small organizations. He holds a BS in Biochemistry from University of California San Diego and a BS in Chemical Engineering from University of California San Diego.



Bill Fox, JD, MA, VP Vertical Strategy Group, CSO Healthcare and Life Sciences, MarkLogic

Bill brings 25 years of experience to the healthcare, life sciences, insurance and technology space. He is an internationally recognized thought leader and speaker on topics related to big data, digital transformation, regulatory compliance, fraud, and data security. Prior to MarkLogic he was an executive at Lexis Nexis, Booz Allen and Change Healthcare where lead complex big data projects in both the commercial and government markets.

Bill is a former law firm partner where he represented the largest insurance companies in the world. As the ex-Deputy Chief of Economic and Cyber Crime at the Philadelphia District Attorney's Office, and a Special U.S. Attorney, he was an early adapter of predictive and graph analytics to understand big data in complex cyber, healthcare and economic crime cases. Bill has served on strategic committees at the NHCAA, AHIP, ABA, HIMMS, MIFA and others.

He has done over 100 presentations, articles and interviews related to big data, data security, healthcare, real world evidence, digital transformation and other related topics.



Alice Augustine - Information Scientist – Taxonomy Management Lead, Amgen

- 20 years' experience in Ag-biotech and Pharma-biotech
- Worked for 17 years in developing and launching biotech corn products at Monsanto.
- Ontologist with >17 years of working knowledge
- Switched from Biological Science to Information Science
- Switched from Ag-biotech to Pharma-biotech.
- Experience in areas of Genomics, Bioreactor cell culture, Plant Breeding, Field Trial Management, Seed Planning and movement, and logistics, Market Research, Product Launch
- Co-founder of Happy Bar Nutrition Inc. a charity that provides nutritious snack bars to children ostracized due to HIV and Leprosy in India



Mark DiMartino – Quality Data Sciences Director, Amgen

Applied data analysis and Data Science Leader experienced leading technical teams that utilize advanced data analysis techniques to solve problems and improve business operations. Skilled in a wide range of operations related activities, including Analytical Method Design, Validation and Transfer, Continued Process Verification, Medical Devices, Comparability, NC/CAPA, and Cross Functional Leadership

BS Cellular and Structural Biology, University of Illinois at Urbana-Champaign
MS Applied Sciences, DePaul University



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REGISTRATION INSTRUCTIONS

For an immediate receipt, please use the Chapter's online processing system:
<http://atdevents.net/register.php>

ISPE LA, SD, SF Members:

If you are an ISPE Member in California, please do not set up a new account, as you should already be in our system. Please email Rob Fleming for assistance with your username and/or password.

ISPE Members of other Chapters:

You will not be in our system unless you have previously set up an account. Please follow instructions for Non Members below. To update your account to a Member account, please forward your confirmation email from ISPE or ISPE Membership Card to Rob Fleming (rob.fleming@yahoo.com). We need your Chapter name, your ISPE Member number and expiration date. You can get your Membership card once logged onto the ISPE website. (Go to "Account/My Account" then "Print Your Membership Card" on left side of the screen towards the bottom).

Non Members:

If you do not have an account on our system, you can set one up on the site using all letters (no numbers) for your username.

Fax Registration:

Complete the Registration Form with a credit card payment and Fax to (949) 266-8461.

Pay by Check:

If paying by check, please register online to hold your spot. Then mail your check no later than one week prior to the meeting to ensure it is received in time. Make checks payable to:

ISPE Greater Los Angeles Chapter, 5319 University Dr., Suite 641, Irvine, CA 92612. Tax ID#95-4452996

Registration Help, setting up your account, having problems with online registration, need to reset your password, questions regarding registration or receipts? Email Rob Fleming (rob.fleming@yahoo.com).

Cancellations must be received in writing via fax or email to Rob Fleming by May 1, 2019 for refund. After the cancellation date if you have reserved a space but do not attend, your payment **MUST** be remitted, however, an alternate person may attend in your place.

To Select a Table for Vendor Night Online:

<http://atdevents.net/register.php>

1. Begin by selecting the type of table you would like (Premium or Regular).
2. On the next screen there is a pull down box showing you the available tables in that category.
3. Select your table number from the pull down box. (Only the available table numbers are shown, if a table number is not listed that means it's already been reserved by another company.)
4. After selecting your table, scroll down to payment options.
5. Select the payment option of your choice and follow instructions to pay. Make sure to go through all of the steps until payment is confirmed. Since our site has to go to the merchant account site, there are a couple extra clicks involved.

REGISTRATION FORM

Register online: <http://atdevents.net/register.php> or fax this completed form to 949-266-8461

ISPE Greater Los Angeles Chapter, 5319 University Dr., Suite 641, Irvine, CA 92612 - Tel: 949-387-9046 - Tax ID#95-4452996

ITEM		AMOUNT	TOTAL
Premium (PR) Table Top (Light Blue tables on diagram)	Includes 2 Attendees	\$1,045	
Regular (R) Table Top (Dark Blue and Green tables on diagram)	Includes 2 Attendees	\$895	
Attendee: Includes Exhibit Show, Technical Session, One Drink and Light Dinner	# of Attendees _____	\$20	
Package of 10 Attendees: Includes Exhibit Show, Technical Session, One Drink per person and Light Dinner	# of Attendees _____	\$120	
Students		Free	
TOTAL AMOUNT DUE			

Type of Credit Card	<input type="checkbox"/> Visa <input type="checkbox"/> MasterCard <input type="checkbox"/> AmEx <input type="checkbox"/> Discover
Credit Card Number	
Expiration Date	
Name on Card	
Signature	
Company Name	
Top 10 Table Selections	
Exhibit Coordinator Name	
Exhibit Coordinator Email	
Address, City, State, Zip	
Office Phone Number	
Cell Number	

MAIN FLOOR

Entrance

TICKETS
(E) CLOAK ROOM

BAR

Women's Restroom

Men's Restroom

PR1

(E) ENTRY LOBBY
[101]

PR2

(E) STAIR 1

(E) EXIT VESTIBULE #1

(E) STAIR 6

(E) STAIR 2

(E) EXIT VESTIBULE #2

(E) STAIR 3

PR20

(E) ICE MACHINE ROOM #2
[114]

PR8

PR9

PR11

PR13

PR15

PR17

PR18

PR19

PR21

PR22

PR24

PR26

PR28

PR29

PR31

PR32

PR35

PR36

PR37

PR38

PR39

PR41

PR42

PR44

PR45

PR47

PR49

PR50

PR52

PR53

PR54

PR55

PR56

(E) ICE MACHINE ROOM #1

PR40

PR41

PR42

PR44

PR45

PR46

PR47

PR49

PR50

PR52

PR53

PR54

PR55

PR56

(E) BAR #1
[104]

PR52

PR53

PR54

PR55

PR56

(E) STAIR 10

(E) EXIT WALKWAY #1
[111]

(E) BAR #2
[105]

PR3

PR4

PR5

PR6

PR7

(E) STAIR 5

(E) STAIR 9

(E) EXIT WALKWAY #2
[112]

(E) STAIR 4

(E) STAIR 9

(E) STAIR 4

(E) STAIR 9

(E) STAIR 4

(E) STAIR 9

Stage

Exhibitor Loading/Unloading

FOOD SERVED

(E) LOUNGE B
[103B]

(E) STAIR 13

(E) TRASH ENCLOSURE
[108]

Women's ADA Restroom

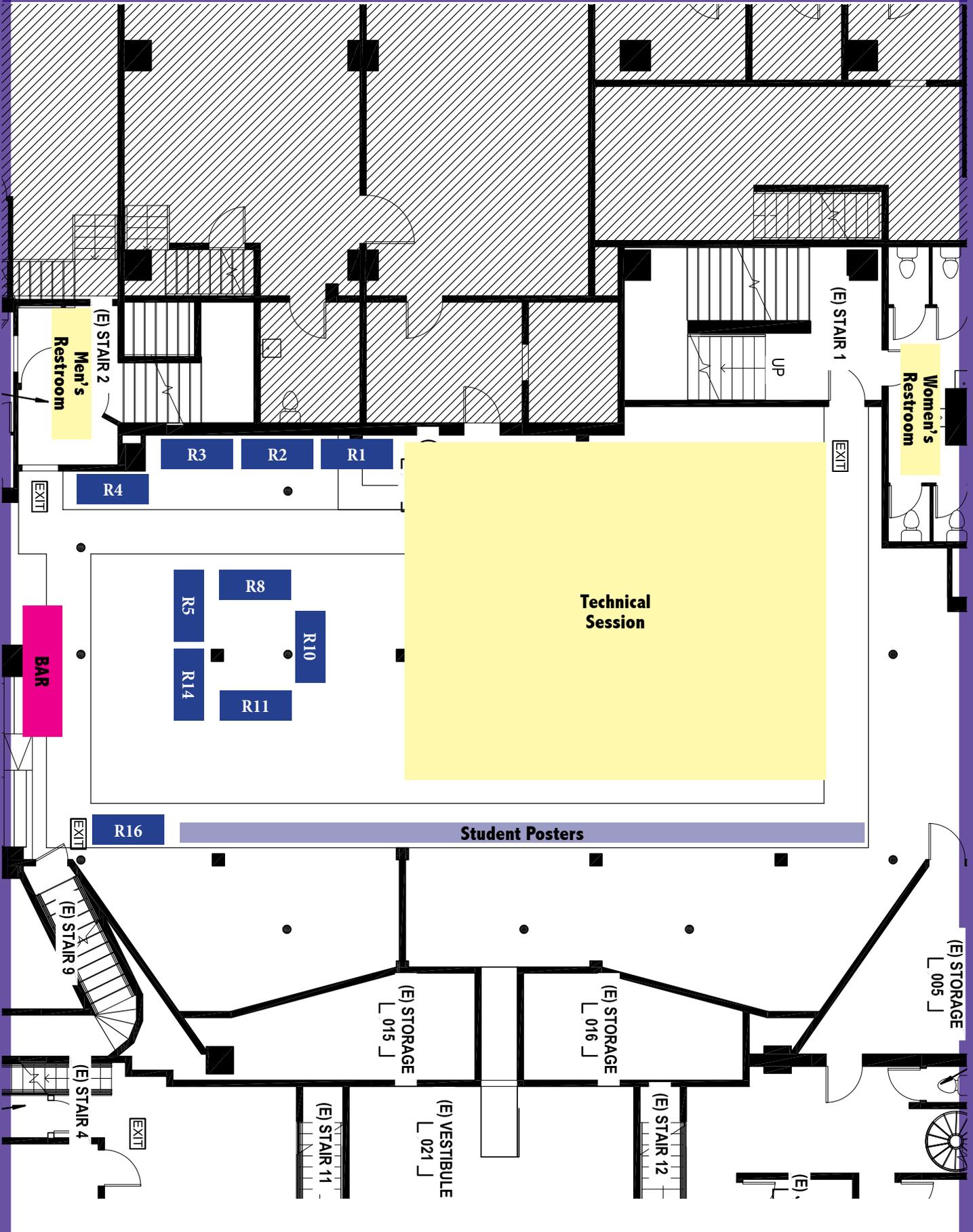
Men's ADA Restroom

Women's ADA Restroom

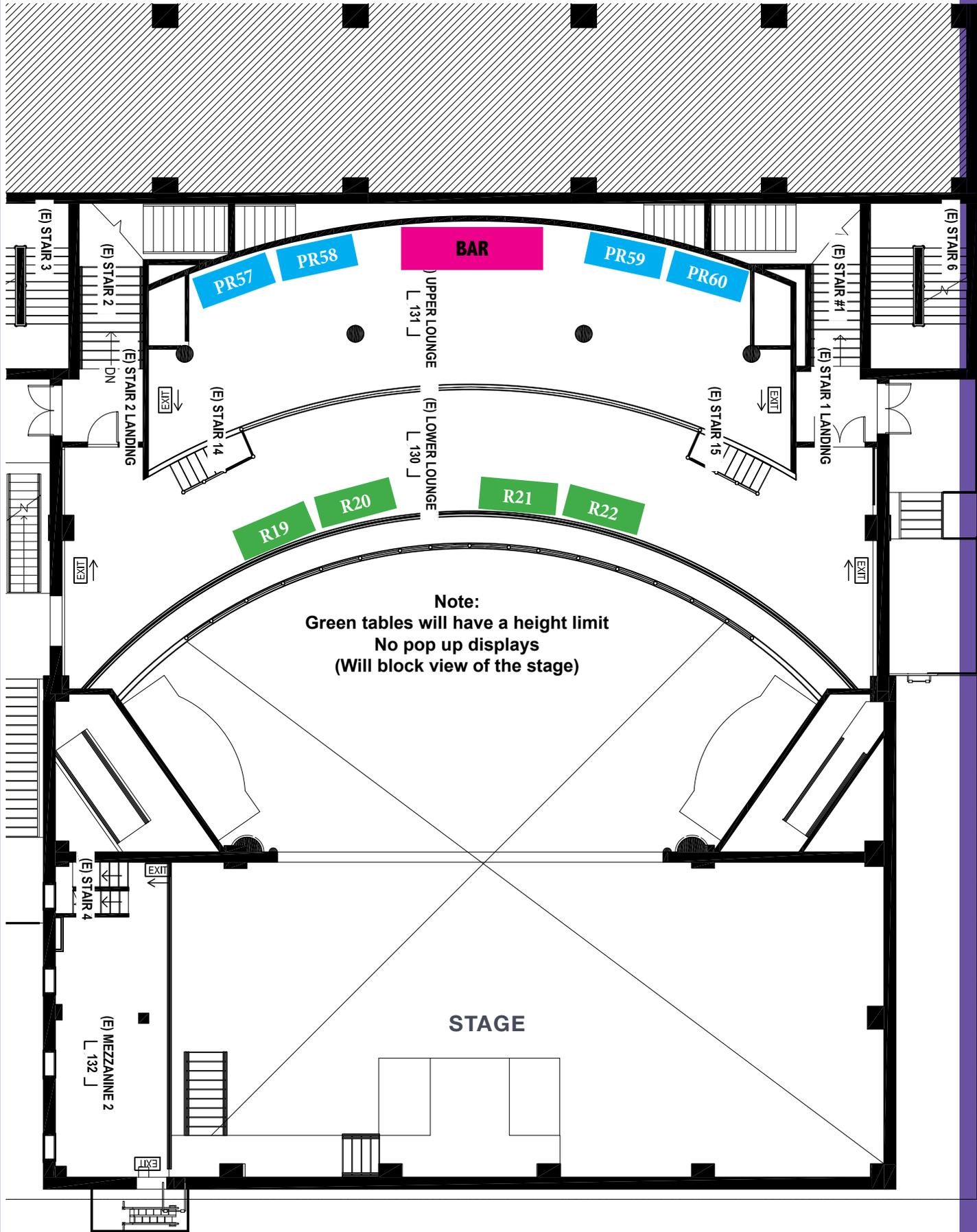
Men's ADA Restroom

(E) ± 18' - 7" V.L.F.
(E) ± 17' - 4" V.L.F.
(E) ± 18' - 7" V.L.F.
(E) ± 17' - 4" V.L.F.
(E) ± 14' - 8" V.L.F.
(E) ± 19' - 11" V.L.F.
(E) ± 16' - 3" V.L.F.
(E) ± 16' - 2" V.L.F.
(E) ± 16' - 11" V.L.F.

LOWER LEVEL



BALCONY



BAR

PR57

PR58

PR59

PR60

UPPER LOUNGE
L 131

LOWER LOUNGE
L 130

R19

R20

R21

R22

Note:
Green tables will have a height limit
No pop up displays
(Will block view of the stage)

STAGE

(E) MEZZANINE 2
L 132

(E) STAIR 3

(E) STAIR 2

(E) STAIR 2 LANDING

EXIT

(E) STAIR 14

(E) STAIR #1

(E) STAIR 1 LANDING

EXIT

(E) STAIR 15

(E) STAIR 6

EXIT

EXIT

(E) STAIR 4

EXIT

EXIT

List of Attendees Needed: Each exhibitor receives two attendees. Additional attendees will be \$20 each. Please email an Excel list of your guests along with payment if you have not already paid online. Please make a separate column for first name, last name, company and email address, then mail to: rob.fleming@yahoo.com

Set Up Time: Noon - 2:00 pm

Loading and Unloading: Pull into the alley behind the Globe Theatre to unload your exhibit materials. You will need to unload your items then park your car in the structure next door (will be accessible from the alley). Then return to bring your materials into the show. If you have another person with you, one can take your exhibit materials to your table while the other parks the vehicle. There will be security in the alley and helpers to assist you with your items if needed. At the end of the event after tearing down your table display, you can pull into the alley again to load your vehicle. Please do not attempt to unload in front of the theater.

Table Size: 6' long by 2.5' wide

The following restrictions for table tops are set by ISPE Headquarters:

- 1) Exhibits must be staffed at all times during exhibit hours. Exhibitors may not take down display before closing hours.
- 2) Exhibits must conform to the following:
 - The entire display must be confined to the top of the table only (nothing will be allowed to hang off, behind, or along side).
 - The maximum height of any display shall be 60" above the table top including lights, signs, etc. However, taller roll up displays will also be allowed on the table or on the floor directly against the back of the table (looking as if it is part of the table).
 - The maximum width of any display shall be 72". Displays must not overhang top of the table.
 - Only static displays are acceptable. No operating machinery of any type will be allowed, however, computers are acceptable.
- 3) ISPE reserves the right to restrict table top exhibits which are objectionable because of size, noise, glaring or flashing lights, method of operation, or any reason and, therefore, to prohibit or evict any exhibitor who, in the opinion of ISPE, may detract from the overall good of the exhibit. This reservation includes person, conduct, printed matter or anything ISPE judges to be objectionable.
- 4) Any failure to comply with the above restrictions may result in exclusion from participation in future ISPE table top events.

Shipping Information: There is no shipping to or from the venue. All display materials need to be brought with you to the venue and taken by you at the end of the event.

Hotels: We do not have a room block for sleeping rooms. There are lots of big chain hotels and boutique hotels in DTLA.

Food and Beverage: No food or beverage of any kind shall be permitted to be brought into the premises. Exhibitors can hand out candy at their table, but not food or drinks.

Damages: The exhibitor(s) will be financially responsible for repair of any damage to walls, floors, permanent fixtures or furnishings.

Garbage and Trash Removal: Please remove all materials and empty cartons from your exhibit area upon conclusion of the event. All materials should be removed from exhibit areas when unattended. Neither ISPE nor the hotel are responsible for lost, damaged or stolen articles.

Signage: Items may NOT be affixed to walls with nails, push pins, tape, staples, or by any other means.

Smoking: Smoking is not allowed indoors. There is an outdoor smoking area. Inquire with the bartender.

These are table tops only, not exhibit booths. We have found that since these are small table tops, many vendors stand in front of their tables eliminating a barrier between you and your potential clients. Each table will be covered, however, you are welcome to bring your own table cover. Please let us know if you do not need a table cover. Your entire display must fit on your table with no items on the floor. Please see the next page which are guidelines established by ISPE explaining the maximum size of displays. Chairs will be available for those needing them.

Electricity: Each table will receive access to one plug, please bring a power strip and extension cord if more plugs are needed.

Pass The Word: This is your show. Please tell everyone in the industry about our event. We are competing with many other shows and to continue our success, we need your help. Please forward the event email to people you are in contact with at local biotech, pharmaceutical, medical device and related industry firms.