

THE BRIDGE

WOMEN
IN PHARMA®

News and Information for ISPE Chapter and Affiliate Women in Pharma® Leaders



Welcome Leaders

Welcome to the August 2020 issue of **The Bridge**, an ISPE Women in Pharma® (WIP) monthly newsletter developed to open the lines of communication among ISPE Chapter and Affiliate WIP leaders, to provide news of importance, share ideas and best practices, and to ensure WIP leaders are kept informed of helpful information as well as updates in ISPE policies and procedures.

Q&A

Our Affiliate does not have a virtual platform?

[Read more...](#)



Highlights

WIP Promotion Code

[Read more...](#)



ISPE Foundation

Women in Pharma® COVID-19 Project

[Read more...](#)

Remote Working: Culture Leadership Evolution

A Message From the ISPE Steering Committee

Alice Redmond, ISPE Women in Pharma® 2020 Steering Committee—EU Representative



The key to a successful organization is having a culture based on a strongly-held and widely-shared set of beliefs that are supported by strategy and structure. Strong company values are even more important in a virtual environment because it helps remote workers separate their work from their life in the same environment. So, when they log on virtually, they must feel like they ‘belong’ and have a strong connection to their colleagues and their company; it is a great motivator when beginning work each day.

We cannot assume our company culture translates remotely, so communication and connection should be emphasized. It should also be built upon transparency and trust: remote employees must be trusted to do more self-directed work. Managers must trust their employees and move away from directing their work to mentoring and coaching them to success by focusing on employees’ work product and outputs rather than strict processes. Culture overcomes all other necessities when it comes to creating an effective long-term remote working strategy. Moving to a remote workforce requires a different mindset, and leadership must focus on trusting their people. This

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WIP ZOOM Sponsorship!



pharmatech[™]
associates

Great news! **Pharmatech** has provided a generous sponsorship that will enable all WIP virtual activities—networking events, webinars, panel discussions, book clubs,

etc.—to be hosted on a Zoom platform that will belong to ISPE WIP. Thank you, Pharmatech, for providing an essential platform to keep ISPE WIP connected, collaborative, and engaged with its global community! ❖

Goal Met! 20 Mentor Circles in 2020!!!

ISPE Women in Pharma® is delighted to announce that it has met its 2020 goal of establishing 20 Mentor Circles by the end of 2020! As of August 2020, the following ISPE Affiliates/Chapters have active Mentor Circles:

ISPE Boston • ISPE CaSA • ISPE Delaware • ISPE Ireland • ISPE Australia
• ISPE San Francisco/Bay Area • ISPE Indonesia • ISPE Philippines • ISPE India • ISPE Mexico • ISPE Argentina • ISPE Brazil • ISPE UK/Denmark/Belgium/Nordic • ISPE Midwest • ISPE Rocky Mountain • ISPE Japan • ISPE Great Lakes • ISPE Pacific Northwest • ISPE Italy • ISPE Russia

Tanya Sharma, WIP Mentor Circle Lead, continues to work with more regions to establish Mentor Circles and anticipates at least five more, around the globe, by the end of this year. Congratulations, Tanya and all WIP Mentor Circle leaders! ❖

WIP Promotion Code for New Industry Members Now Available



2020 WIP Promotion

Are You Interested in Becoming Part of WIP?
Join ISPE today to support this exciting initiative.
Use code **JOINWIP** to waive the \$40/€35 processing fee on an ISPE full industry Membership.

ISPE.org/JOIN

Offer valid through 31 December 2020

ISPE has developed a code that ISPE Chapters and Affiliates can offer to new industry members joining ISPE who plan to participate in Women in Pharma®. This code will enable them to waive the processing fee for new members (\$40/€35) and is good through 31 December 2020.

Each ISPE Affiliate and Chapter, and each WIP leader, has received a flyer and a slide that can be used when recruiting potential new members. If you do not have these, please reach out to **Debbie Kaufmann** (dkaufmann@ispe.org). ❖

Q: Our Affiliate does not have a virtual platform to use for WIP Mentor Circles. What should we use as we move forward with these and other WIP virtual events?

A: As announced under Highlights in this issue of The Bridge, Pharmatech has provided a sponsorship to cover the costs of a Zoom platform for use by all ISPE Chapter and Affiliate WIP groups. Each region will have its own license to share with any WIP group within that region to use for any WIP virtual event, including Mentor Circles, webinars, panel discussions, and networking events.

You will receive information and instructions on how to obtain a license for your use when holding a WIP Virtual Program.

Please remember to thank Pharmatech, verbally and with a cover slide (which will be provided by ISPE) at any of these virtual events. Again, our thanks to Pharmatech for its generosity and support of WIP! ❖

“Don’t be afraid to speak up for yourself. Keep fighting for your dreams!”

—Gabby Douglas

UPCOMING AFFILIATE AND CHAPTER EVENTS AND ACTIVITIES

Women in Pharma® “Mentor of the Month” Event

Hosted by the ISPE Great Lakes Chapter’s WIP Group—September 24, 9:00AM-10:00AM CST



All are invited to participate in the September “Mentor of the Month” event. The topic is **How Self Awareness Can Grow Confidence**. Led by **Sandy Chambers**, Senior Director, Global Supply Chain Brand Management, Abbvie, this virtual conversation will focus on how to convert fear to confidence as we encounter change, and how to define your own personal brand. Join Sandy and the [ISPE Great Lakes Chapter](#) 24 September 2020 9-10 am (CST), for this important program. [Register here.](#) ❖

WIP Group of the Greater Pacific NW Chapter Hosting

Modern Technologies Meets Modern Solutions with Blockchain!

The WIP Group of the Greater Pacific Northwest Chapter invites all to participate in a complimentary virtual webinar on Thursday, 17 September 2020 7:30-10 am (PST). The webinar, **Modern Technologies Meets Modern Solutions with Blockchain!** will feature **Susanne Somerville**, CEO of Chroniced, **Gregg Gorniak**, US Serialisation Market Lead, GSK, **Edgar Roder**, Senior Consultant, Digital Assurance Europe, NNIT, and **Justin Dubinsky**, Partner and Principal Consultant, Computer System Validation, Assurea. Join the webinar to learn about blockchain implementation and assurance. [Register here.](#) ❖

A MESSAGE FROM THE ISPE FOUNDATION

Brazil Affiliate’s WIP Project—Funded by ISPE Foundation

In July, the ISPE Foundation awarded the **ISPE Brazil Affiliate** a \$2500 US **COVID-19 Support Match Grant** on behalf of its **Women in Pharma® COVID-19 project**. The grant funded the Brazil Affiliate’s WIP efforts to create hygiene kits that included personal protection equipment (PPE), hand sanitizer, shampoo/conditioner, soap, dental products, etc., for the homeless population in São Paulo. On August 1st, members from the **ISPE Brazil Affiliate** and WIP Brazil handed out hygiene kits to over 200 individuals in need. In what was described as an emotional day, testimonial from WIP Brazil members demonstrates the ripple effects of performing acts of service and how they impact us and our respective communities.



“The event made our ISPE Affiliate more visible to our society. Many of our colleagues from the pharma industry and other areas are interested in collaborating with us in the future, not limited to COVID-19 efforts, but throughout the entire year. These colleagues are attracted to the mission of Woman in Pharma®.” In addition, the WIP said that “We could never imagine that more than 200 people in a homeless situation could be so sensitive and thankful, especially in a COVID-19 moment. We made t-shirts with our logos and used face masks and gloves to be protected. Some colleagues brought their spouse and children to assist delivering the goods. Some of our members were very emotional. In response, we have made the decision to promote, donate, and contribute to the Gaiivota Social Institute for the Homeless Population every month, because they really need our support.”

The ISPE Foundation is incredibly proud of the ISPE Brazil Affiliate Women in Pharma® program’s achievements! We hope their actions inspire our network of Affiliates and Chapters to take similar steps and apply for a **COVID-19 Support Match Grant**. The application deadline is 1 October 2020. Full guidelines and materials can be found on the [ISPE Foundation page](#).

In addition to the COVID-19 Support Match grant, funds are also available for Student and YP event attendance grant requests. To be eligible for a 2020 Grant, applicants must complete and submit a Grant Request form to the Foundation no later than 1 September 2020. It is our hope that the availability of these grants will enable more students and young professionals to participate in our ISPE events. Interested applicants are able to find the request forms available for download on the [ISPE Foundation page](#).

Donations to the Foundation to support similar grants and programs can be made online at [ISPE Foundation](#). ❖

RECENT EVENTS



ISPE Eurasia Affiliate Launches WIP Book Club

In August 2020, the WIP group from the ISPE Eurasia Affiliate got together and started a

book club! Special guests were sisters from the Yaritzta family, which has led one of the oldest private publishing companies in Russia—SLOVO (which translates to WORD in English)—for more than 30 years. SLOVO’s philosophy is to respect its’ readers, and it creates amazing art albums and special editions for significant art exhibitions. Every book SLOVO publishes looks like an art object!



The Book Club provided the EAEU WIP group the opportunity to ask SLOVO about the publishing business, family business, book clubs, their favorite books, and writers.

The WIP attending the Book Club concluded that in the era of the triumph of visuality, people lose the ability to contemplate. This covers all spheres, among them culture and science. People have sometimes stopped thinking about the meaning of life, and everyone should be able to stop for at least a few minutes from time to time to look at the world around us. A book has a very important asset: when you leaf through it, you can go back or just stop on a page and re-read the sentence several times. This moment of contemplation of the text is very important.

Throughout the month of September, the EAEU WIP Book Club has two books which offer this chance to contemplate. The first are classics by Rosamunde Pilcher: **A Family Affair or The Shell Seekers**. The second is **On the Couch: A Repressed History of the Analytic Couch from Plato to Freud** by Nathan Kravis. The book examines how the couch became an icon of self-knowledge and self-reflection as well as a site for pleasure, transgression, and healing. At the end of September, the EAEU WIP group will meet again to share the thoughts and feelings the members gained from reading these books. ❖

To all the ISPE Chapter and Affiliate WIP and WIP Mentor Circle leaders—we appreciate your enthusiasm, flexibility, and creativity during the time of COVID-19. These online programs are enabling everyone to remain engaged, continue to learn, and maintain connections and collaboration. Thank you!

WIP Group of the Greater Pacific Northwest Chapter “Practical Guide for Data Integrity Assessments” Webinar

ISPE Pacific Northwest Chapter
Practical Guide for Data Integrity Assessments

Agenda:
8:30 – 8:35 am: Opening and Introductions
8:35 – 9:05 am: Data Integrity Maturity Assessments by David Thompson and Helen Bickley
9:05 – 9:15 am: Q&A
9:15 – 9:45 am: Practical Guide on Data Integrity Assessments by Shirlee Hart
9:45 – 9:55 am: Q&A
9:55 – 10:00 am: Closing and Survey

Date: Monday, August 31st 2020
Time: 8:30 am - 10:00 am PST

Registration:
<https://us02web.zoom.us/j/802272017201>
<http://dx.doi.org/10.26434/chemrxiv-2020-77201>

JOIN US FOR A COMPLIMENTARY VIRTUAL WEBINAR TO LEARN ABOUT DATA INTEGRITY ASSESSMENTS FOR COMPUTERIZED SYSTEMS AND REAL-WORLD APPLICATIONS FOR FDA 21CFR COMPLIANCE REQUIREMENTS.

Meet Our Experts:

Helen Bickley Vice President of Quality Operations, Fujifilm Diosynth Biotechnologies	David Thompson Owner and Principal Consultant, Clarity Compliance Solutions Ltd.	Shirlee Hart Owner and Laboratory Informatics Consultant, SMHart Systems
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On 31 August 2020, the WIP Group of the Greater Pacific Northwest Chapter hosted a complimentary webinar entitled **Practical Guide for Data Integrity**

Assessments. **Helen Bickley**, VP, Quality Operations, Fujifilm Diosynth Biotechnologies, **David Thompson**, Owner and Principal Consultant, Clarity Compliance Solutions, Ltd., and **Shirlee Hart**, Owner and Laboratory Informatics Consultant, SMHart Systems, shared their expertise about data integrity assessments for computerized systems and real-world applications for FDA 21CFR Compliance Requirements. ❖

ISPE congratulates its Japan and India Affiliates on successful starts to their WIP Programs. Good luck and keep us posted on future events and activities!

Japan Affiliate WIP Program Kick-Off Held in August

The ISPE Japan Affiliate kicked off its WIP program on 25 August 2020, with a meeting that included 4 mentors and 6 mentees. Ground rules and global activities of the WIP mentor circle were introduced to mentees, and the group discussed how to operate WIP activities in Japan. They also discussed whether a paradigm shift of work style resulting from COVID-19 affects work-life balance and social advancement of women in Japan. The Japan Affiliate’s WIP group is planning Mentor Circles and other activities in the future...stay tuned for more information and details. ❖

India Affiliate Launches WIP Program

In mid-June, the ISPE India Affiliate launched its WIP program. Approximately 10 ISPE industry members participated, with more showing interest and included in a more recent session held in late August. The Affiliate has formed a core WIP team, which is excited about the initiative, and members are calling for global participation. Topics being planned for discussion include work-life balance, success stories with practical inputs, stress management, and networking. ❖



includes offering more autonomy, entrusting the decisions made by individuals and teams, improving transparency through better communication skills, and holding people accountable.

OK, now for a reality check! A widespread and permanent shift to remote working will not occur seamlessly; it will require leaders to be thoughtful and deliberate, creating work practises designed for a workforce that can truly work remotely or in a hybrid way!

Dynamically Supporting Culture in a Remote Environment Has a Few Key Prerequisites:

EVOLUTION OF THE LEADERSHIP TEAM—Managing remote teams is a skill that goes beyond being able to work from home. In fact, it requires a whole different set of traits, practices, and strategies compared to managing a team located within the same office. A lot of this is transferable, but every remote manager must evolve, learn, implement, and practice to successfully lead remote teams. Companies need to develop individualised programs to facilitate this transition.

ESTABLISH A COMMUNICATIONS PLAN—Transparency is key during this time. Team members will expect frequent updates as leaders iterate on their communication plan in real-time. Consider online social events and an always-on conference call per team where team members can ‘hangout’ or come and go as they please. This simulation helps collaboration and informal communication, enabling team members to embrace the move to remote working in a less unsettling way. It also embraces informal communication—an important element that occurs spontaneously in an office and needs an immediate replacement in a remote setting. Maybe develop a handbook that will serve as a single source of truth and communicated company wide. This can reside on the company Intranet and be set up with a chat function whereby news, tips, tools, and lessons learnt can be

added in a dynamic way. One of the biggest challenges when going remote is keeping everyone informed and connected.

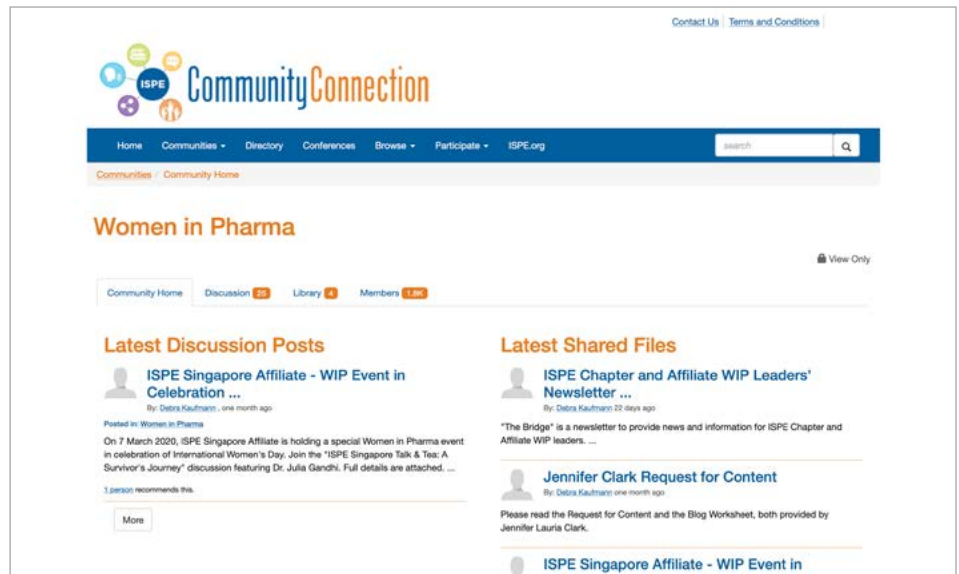
MINIMIZE YOUR TOOL STACK—While functioning remotely, the tool stack needs to be reduced to a minimum. SharePoint, Google Docs, or a company-wide chat tool (like Microsoft Teams), and Zoom are all you need to start. If your team needs access to internal systems through a VPN, ensure that everyone has easy access and clear instructions on usage that suits all levels of technology skill. Leaders may also consider proposing tech “allowances” that help employee purchases of home office necessities, such as ergonomic chairs, printers, or extra monitors, and should ensure employees have access to adequate broadband.

A widespread and permanent shift to remote working will not occur seamlessly; it will require leaders to be thoughtful and deliberate.

DRIVE CHANGE—For companies with a strong “in-office /in-company experience,” it is vital for leadership to recognize that the remote transition is a process. Leaders are responsible for embracing change, being open about what is and isn’t working, evolving the process, and messaging this to all employees. Managing a remote way of working comes down to trust, communication, and company-wide support of shared goals...and company culture reinforcement. ❖

Any donations your Chapter or Affiliate obtains for the ISPE Foundation on behalf of Women in Pharma® will be 100% earmarked for WIP Initiatives! [Visit ISPE Foundation - WIP Initiatives](#) to learn more. ❖

ISPE WIP Community of Practice



The [ISPE Women in Pharma® Community of Practice](#) (CoP) is a great venue for sharing information, asking questions of your fellow WIP Members, and posting items of interest to the WIP Community. If you have not yet joined, be sure to do so today! If you have questions on how to join, please contact Debbie. If you are already a member, start posting! Especially in this time when most of us are working from home and unable to congregate at meetings or conferences, this will help us all keep in touch! ❖

We Need Your Participation to Make This Newsletter Successful!

Please send **Debbie Kaufmann** (dkaufmann@ispe.org) the following information regarding your current and upcoming events and activities by the **15th of each month**:

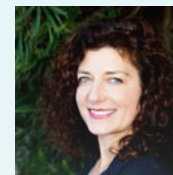
- » Name of your Chapter or Affiliate
- » Current (or very recent) events (conferences, meetings, Mentor Circles, panels, networking events, or other activities)
- » Events planned within the next two months (conferences, meetings, Mentor Circles, panels, networking events, or other activities)
- » For current or very recent events' challenges and outcomes, please provide examples of successes such as metrics (number of people that attended, panelists, any other information of note) and challenges you may have encountered
- » For upcoming events—challenges and important planning aspects
- » Questions you would like answered
- » Any other information you wish to provide.

We look forward to hearing from you! Let's work together to make *The Bridge* a great forum for sharing, communicating, and collaborating! ❖

Thank You!



Jennifer Lauria Clark
ISPE Women in Pharma® 2020 Steering Committee Chair



Stephanie Thatcher
ISPE Women in Pharma® Chapter and Affiliate Liaison