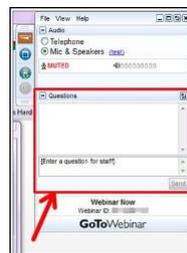




Have Questions?



Type them into questions box!

“Why am I muted?”

Don't worry. Everyone is muted except the presenter and host. Thank you and enjoy the show.

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1



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<https://www.acs.org/content/acs/en/acs-webinars/videos.html>

3



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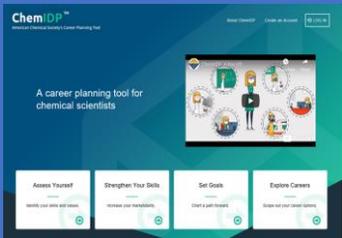
A collection of the best recordings from the ACS Webinars Library will occasionally be rebroadcast to highlight the value of the content.

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4

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ACS Career Navigator: Your Home for Career Services



Whether you are just starting your journey, transitioning jobs, or looking to brush up or learn new skills, the **ACS Career Navigator** has the resources to point you in the right direction.

We have a collection of career resources to support you during this global pandemic:



Professional
Education



Virtual Career
Consultants



ACS Leadership
Development System



Career Navigator LIVE!



ChemIDP



College to Career



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7

Join us in our efforts to increase the diversity of chemistry.



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Chemistry for Life®

8

A Career Planning Tool For Chemical Scientists



ChemIDP is an Individual Development Plan designed specifically for graduate students and postdoctoral scholars in the chemical sciences. Through immersive, self-paced activities, users explore potential careers, determine specific skills needed for success, and develop plans to achieve professional goals. **ChemIDP** tracks user progress and input, providing tips and strategies to complete goals and guide career exploration.

<https://chemidp.acs.org>

9

ACS Bridge Program



Are you thinking of Grad School?

If you are from an underrepresented racial or ethnic group, we want to empower you to get your graduate degree!

The ACS Bridge Program offers:

- A FREE common application that will highlight your achievements to participating Bridge Departments
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10

ACS Department of Diversity Programs

Advancing ACS's Core Value of Diversity, Inclusion & Respect



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11



La Generación de
Combustibles Solares
Mediante Procesos
Fotoinducidos

Fecha: Miércoles, 18 de Agosto, 2021 @ 2-3pm ET

Ponente: Dra. Leticia Myriam Torres Guerra, Centro de Investigación en Materiales Avanzados S.C. (CIMAV)

Moderadora: Dra. Maria del Jesus Rosales Hoz, Cinvestav y Sociedad Química de México

[Regístrase Gratuitamente](#)

Lo Que El Público Aprenderá:

- Procesos de fotoconversión del agua en H_2 y O_2 y en la reducción fotocatalítica del CO_2
- Influencia del método de síntesis de óxidos cerámicos y variaciones cristaloquímicas de estos materiales en la eficiencia fotocatalítica de estos procesos
- El uso de un co-actulizador para mejorar el transporte de cargas y lograr una mayor actividad fotocatalítica

Co-producido con: Sociedad Química de México y *Chemical & Engineering News*

THE
POST-COVID
CHEMISTRY ECONOMY
& DEIR PROGRAM UPDATES

Date: Tuesday, August 31, 2021 @ 1-2pm ET

Speakers: Bill Carroll, Carroll Applied Science / Isiah Warner, Louisiana State University / Rajendran Mukhopadhyay, ACS Office of DEIR / Trinity Horton Hale, Celanese

Moderator: Arlene Garrison, ACS Senior Chemists Committee

[Register for Free!](#)

What You Will Learn:

- Insights on the impact of COVID on the chemistry economy
- Society wide efforts and activities to support diversity, equity, inclusion and respect (DEIR) and a new grant program for senior chemists with creative ideas to address DEIR
- An update on SCC activities and story from the ACS Scholars Program

This special broadcast is produced for the ACS Senior Chemists Committee by ACS Webinars.

Skydiving into Retirement
How to Actively Manage the Transition

Date: Wednesday, September 8, 2021 @ 2-3pm ET

Speaker: Bill Carroll, Carroll Applied Science

Moderator: Tom Halleran, American Chemical Society

[Register for Free!](#)

What You Will Learn:

- How your persona changes when you retire
- Why it's important to actively structure your retirement
- Some useful tools for retirement success

Co-produced with: ACS Careers

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12

ACS Green Chemistry Institute



Engaging you to reimagine chemistry and engineering for a sustainable future!

We believe sustainable and green chemistry innovation holds the key to solving most environmental and human health issues facing our world today.

- Advancing Science
- Advocating for Education
- Accelerating Industry



ACS GCI convenes **companies in the chemical industries to advance the implementation of sustainable and green chemistry and engineering.**

<https://www.acs.org/gciroundtables.html>

gciroundtables@acs.org

13

16 YEARS of Advancing GC&E in Pharma and Beyond



12 Collaboratively developed, high-quality tools & metrics

\$2.4 Million given in research grant funding

Funding of **28+** research programs around the globe

Leveraged **\$1.3 Million** from Federal Agencies

41 Symposia organized since 2016

Supporting travel of **75** professors & **31** students to present research since 2014

17 Educational workshops & webinars since 2017

80+ Publications resulting from funded research, **1700+** unique daughter citations

49 Roundtable authored papers since 2007

The Peter J. Dunn Award for Green Chemistry & Engineering Impact in the Pharma
Established in 2016

- Bridging the gap between academics & industry
- Enabling better decisions about chemical selection process design
- A leading voice for GC&E
- Inspiring and educating the next generation
- Recognizing excellence in GC&E

<https://www.acsgcipr.org>

14



ACS
Chemistry for Life®

co-produced with: ACS Green Chemistry Institute

Enabling Greener Pharma Manufacturing

Scaling a Photo-Flow Bromination for Belzutifan



FREE Webinar | **TODAY** at 2pm ET



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15



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ACS
Chemistry for Life®

Enabling Greener Pharma Manufacturing: Scaling a Photo-Flow Bromination for Belzutifan



John Tucker

Executive Director, Chemical Development,
CMC, Neurocrine Biosciences



Cecilia Bottecchia

Senior Scientist, Merck



François Lévesque

Principal Scientist, Merck

Presentation slides are available now! The edited recording will be made available as soon as possible.

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This ACS Webinar is co-produced with ACS Green Chemistry Institute and the ACS Green Chemistry Institute Pharmaceutical Roundtable.

16

Membership 2021



acsgcipr.org

17

Award Recognition Today



Academic awards are many and focus on novelty and publication

- Holistic (process) strategies are often shunned in favor of specific methodology
- Green chemistry has yet to fully penetrate academia
- Process development is not a discipline taught in academia, but is learned on-the-job through mentorship and experience

Companies may be less likely to share advances in chemistry as the business model does not support publication as a final deliverable

- There is a risk to any disclosure i.e., IP or trade secrets

Academics drive most public acknowledgement of science

- Subsequently, there are few opportunities for recognition of green process chemistry

Why a Process Green Chemistry Award?



ACS Green Chemistry Institute
Pharmaceutical Roundtable

A phalerist is someone who studies awards

- Dr. Jana Gallus holds a Ph.D. in Economics from the University of Zurich, is a UCLA professor at the Anderson School of Management, and a phalerist of some renown
 - Consider reading her paper entitled "[Awards, Honors and Ribbons: Between Fame and Shame.](#)"

There are various reasons why people give awards

- To establish a legacy, e.g., Alfred Nobel and the Nobel Awards
- To shape a field and influence the direction that it takes, e.g., The Academy Awards—in a subjective medium, establishes what is considered high quality, influencing the future production of movies

With the Peter J. Dunn Award, the ACS GCIPR seeks to transform the way green process chemistry is viewed, exemplified, measured and acknowledged...for the inspiration of future science.

J. Tucker

acsgcipr.org

Recognizing Exemplary Industrial Green Chemistry Innovation



ACS Green Chemistry Institute
Pharmaceutical Roundtable

Peter J. Dunn Award for Green Chemistry and Engineering Impact in the Pharmaceutical Industry

- Established in 2016 to recognize outstanding industrial development or implementation of novel green chemistry and/or engineering in the pharmaceutical industry that demonstrates compelling environmental, safety, cost, and/or efficiency improvements over current technologies at significant scale
- Award consists of a plaque and an invited lecture at the ACS Green Chemistry Institute's Annual Green Chemistry & Engineering Conference (travel reimbursed up to \$2,500)
- **Submissions open through Dec 31 each year at acsgcipr.org/awards**

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Inspiring Global Green Chemistry



2022 GCIPR CMO Award for Excellence in Green Chemistry

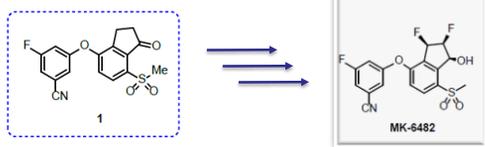
- **Eligibility specific to Asia** — seeking to inspire the global pharma supply chain
- Recognize outstanding efforts toward pharmaceutical green chemistry as performed by Asian CMO companies in support of research, development and manufacturing demonstrating compelling environmental, safety and/or efficiency improvements.
- Award consists of a plaque and an invited lecture at the ACS Green Chemistry Institute's Annual Green Chemistry & Engineering Conference (travel expenses up to \$2,500)
- **Submissions open through Dec 31 at acsgcipr.org/awards**

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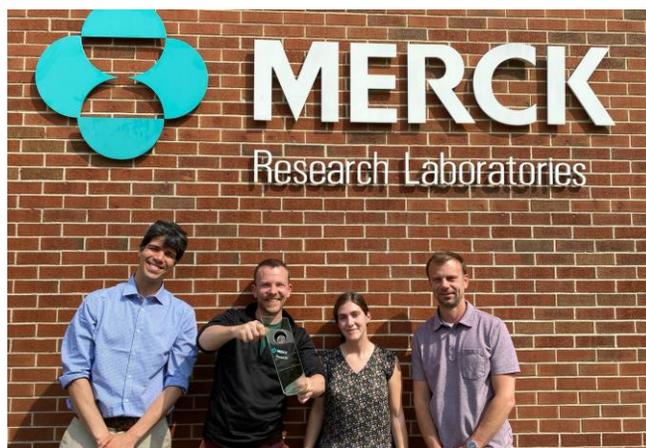
The 2021 Peter J. Dunn Award

*Greener Manufacturing of Belzutifan (MK-6482)
Featuring a Photo-Flow Bromination*



Presented to:

Stephen Dalby, Ph.D.
Cecilia Bottecchia, Ph.D.
Francois Levesque, Ph.D.
Jonathan McMullen, Ph.D.



2022 Nominations open: www.acsgcipr.org/awards

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ACS
Green Chemistry
Webinar

August 12th, 2021

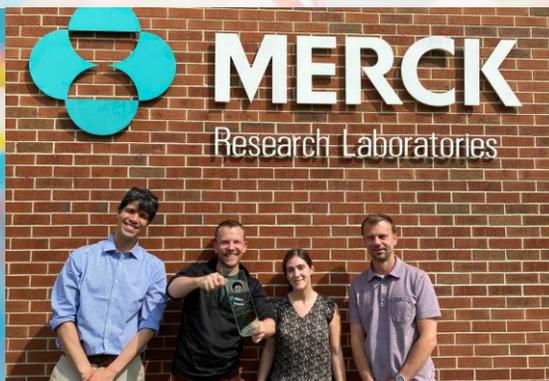
Enabling Greener Pharma Manufacturing

Scaling a Photo-Flow Bromination for Belzutifan

Cecilia Bottecchia, François Lévesque

Stephen Dalby & Jon McMullen

Merck Process R&D



We follow the science

We believe it is our responsibility to deliver healthier tomorrows through our vaccines, medications and animal health products that can help patients and communities around the world.

Core growth drivers:

Oncology
Vaccines
Hospital, specialty and chronic care
COVID-19

Animal Health:

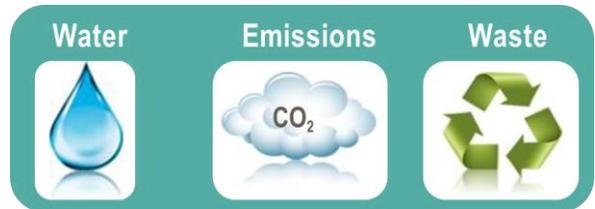
Companion animal
Livestock

Commitment to Green & Sustainable Manufacturing



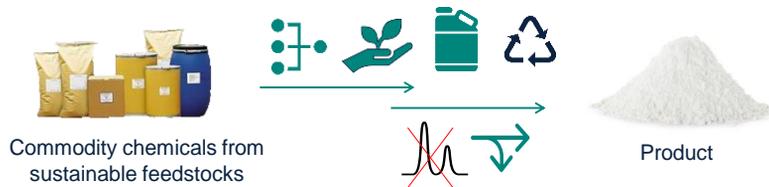
“Our passion to save and improve lives extends to our commitment to protecting and sustaining the environment.”

“We will minimize our environmental footprint through scientific innovation.”



Commercial Process Development Mission

Our aspirational goal
Develop idealized manufacturing processes

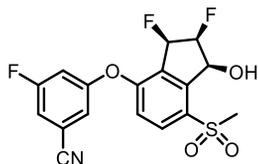


How to get there
Innovations in process chemistry

- Green & Sustainable processes *by design*
- Scientific creativity – inventing solutions to solve problems
- Innovative technologies for future manufacturing



Belzutifan



- Oral HIF-2 α inhibitor for treatment of renal cell carcinoma & non-RCC tumors
- Asset from acquisition of Peloton Therapeutics in mid 2019
- Awarded breakthrough status designation by FDA

Bringing Belzutifan to patients on a highly accelerated timeline

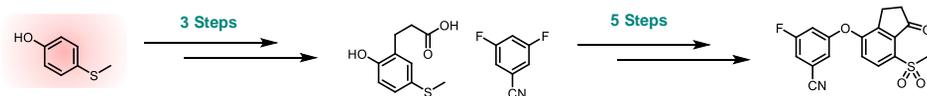


- Commercial process development & validation in <18 months
- Strategic focus for process re-design
- Commitment to Green & Sustainable goals

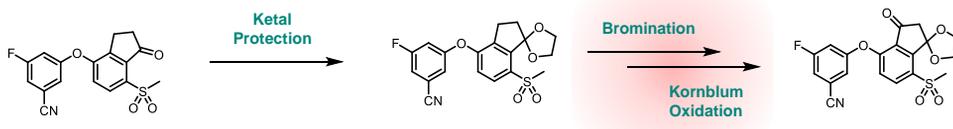


Inherited Clinical Supply Process

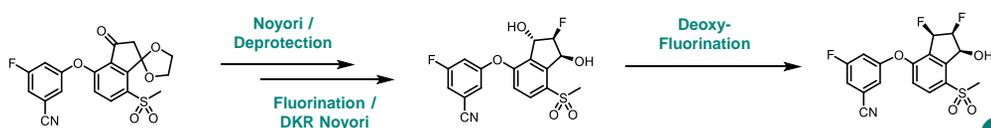
Indanone Core Synthesis (RSM)



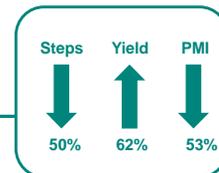
Mid-Game



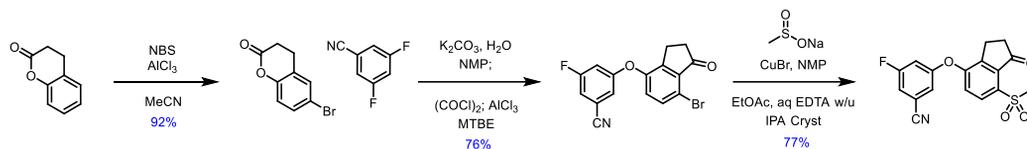
End-Game



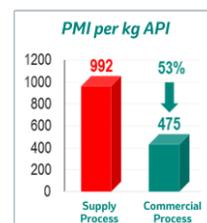
Delivering a Greener Commercial Process



Indanone Core Synthesis (RSM) - Develop concise new route

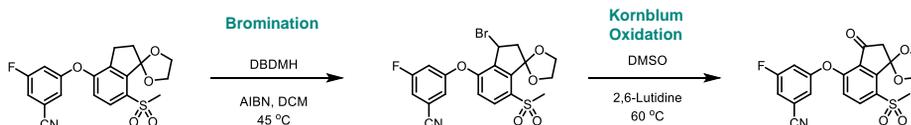


- Dihydrocoumarin as commodity RM
- 4 step process, 3 crystallizations
- Rapidly developed for 1MT campaign in ~4 months



Bromination / Oxidation – The Major Issue

The Problem



- Batch instability risk
- Hazardous Reagent
- Chlorinated solvent

Mutagenic –
Handling safety

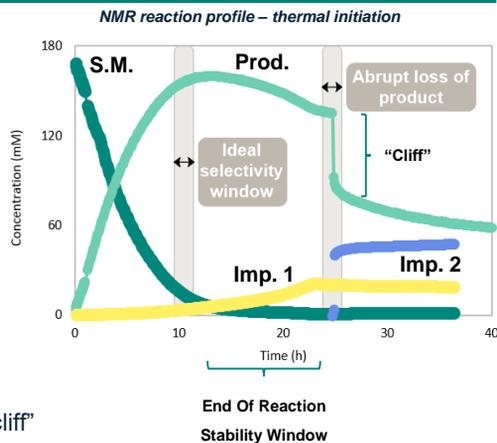
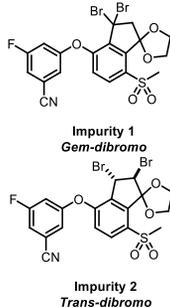
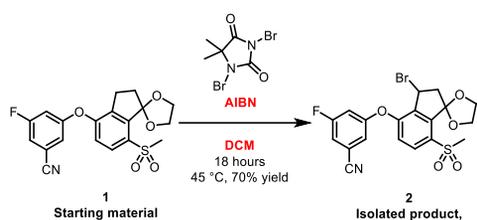
- Thermal safety hazard
- Me₂S byproduct – Stench
- Non-preferred solvent

Objectives

- Safe, Robust & drastically Greener conditions for both steps
- Single solvent through process & avoid bromide handling



Challenges with radical Bromination



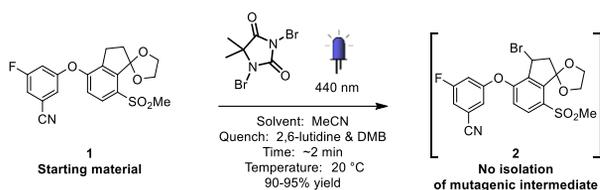
- Serious robustness liability
- Unstable end of reaction mixture – short time window before “cliff”
- Elevated temp shrinks stability window

Are there better ways to make this radical?



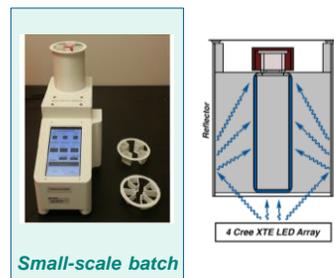
31

Photobromination route: Proof of concept



Photochemistry identified as an enabling technology for this reaction

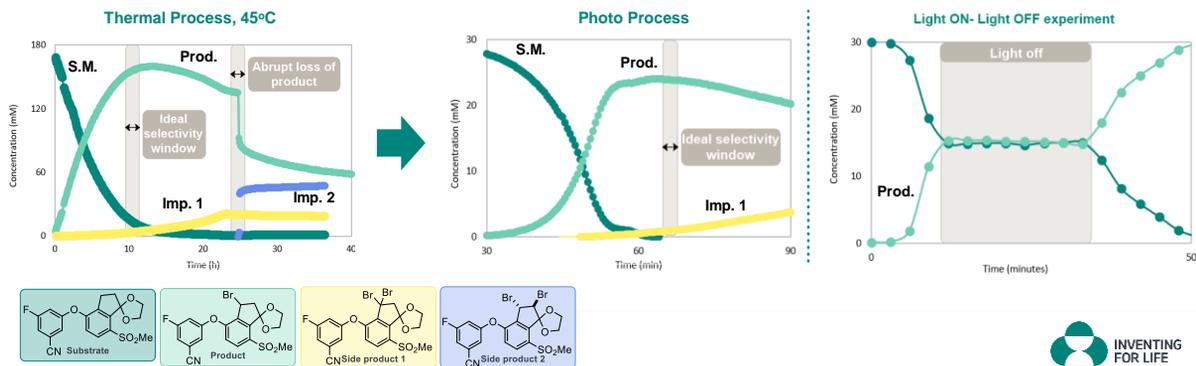
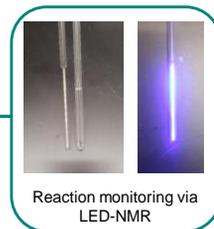
- Replaced chlorinated solvent with MeCN
- Ambient temp - Improved reaction selectivity and stability
- Initiation successful at different wavelengths (312 – 520 nm)



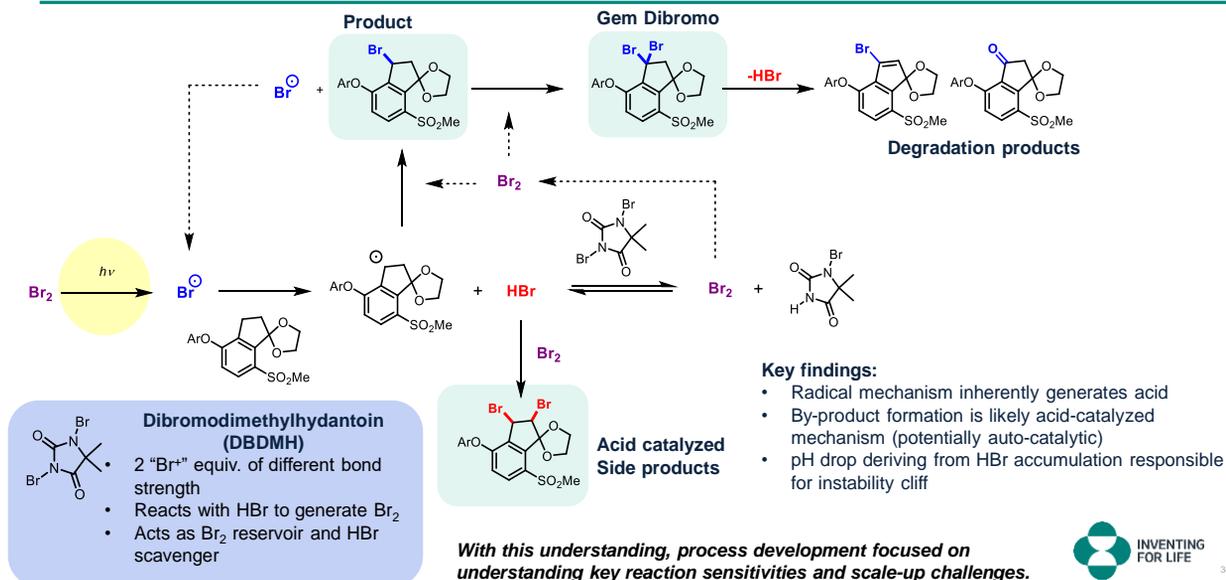
32

Understanding the benefits of photochemistry

- Key reaction insight achieved by monitoring via photo-NMR.
 - Photochemistry is not a panacea for robustness but pushes failure cliff far from operating conditions.
 - Reaction can be turned on and off with the flick of a switch.



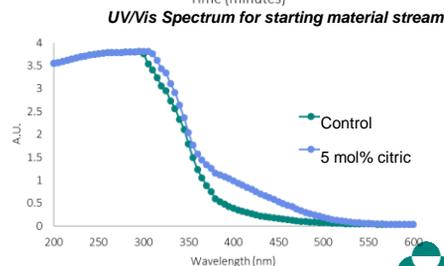
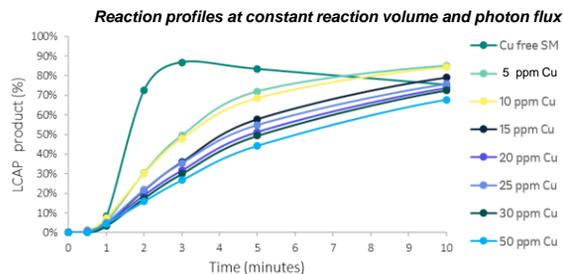
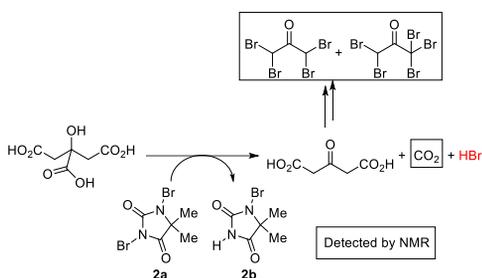
Photochemical bromination – Mechanistic considerations



Process development highlights: sensitivity to starting material quality

Understanding the impact of upstream processing on starting material quality is critical for process robustness.

1. Colored impurities affect initial reaction Abs → carbon treatment implemented to normalize Abs
2. Identified residual copper as strong inhibitor
 - Numerous copper chelator screens were performed, leading to citric acid as a hit.



Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT



In your opinion, what is the biggest challenge in scaling up photochemistry?

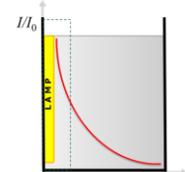
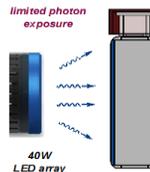
- Resistance to change – implementing new technology takes time
- Energy and cost requirements compared to thermal processes
- Availability of powerful light sources
- Limited light penetration through a solution
- Other (Tell us more in the chat!)



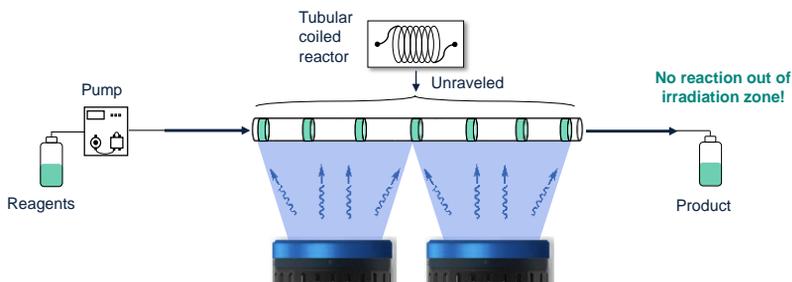
The grand challenge: scaling up photochemistry

Ideal reactor requirements:

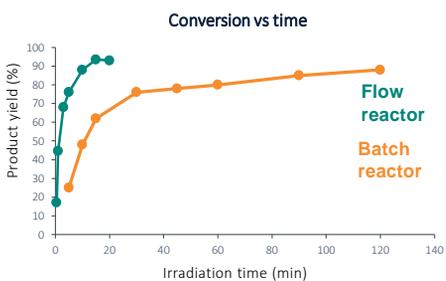
- Powerful LEDs and a reactor design that limits “dark zones.”
- Tight control of reaction time.
- High heat transfer rates to minimize reaction stability risk.



These are all drivers to use flow chemistry in production, but how can we transfer from batch to flow?



Photon stoichiometry: a key parameter across scales

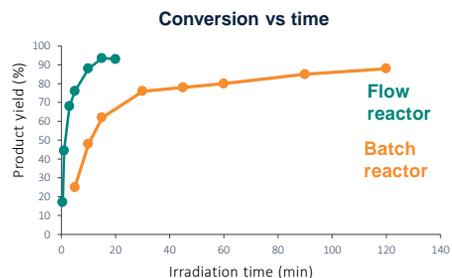


Why are batch vs flow reaction profiles so different?
 Reactors vary in terms of:

- * Volume
- * Surface area
- * Geometry
- * Light source



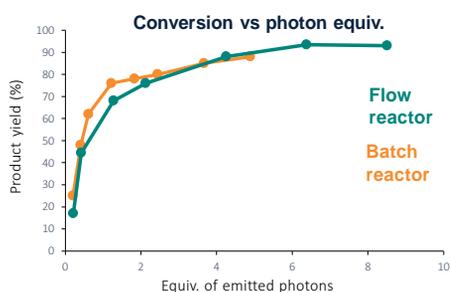
Photon stoichiometry: a key parameter across scales



Why are batch vs flow reaction profiles so different?

Reactors vary in terms of:

- * Volume
- * Surface area
- * Geometry
- * Light source



Photon stoichiometry
can be used to

- * Predict reaction time across reactors
- * Inform on reactor design/efficiency

Bonfield, H.E., Lévesque, F. *et al.* *Nat Commun* **11**, 804 (2020).
Corcoran, E. B.; McMullen, J. P.; Lévesque *et al.*, *ACIE*, (2020), DOI: 10.1002/anie.201915412.

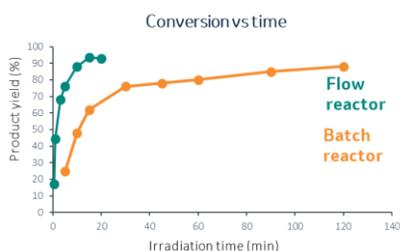


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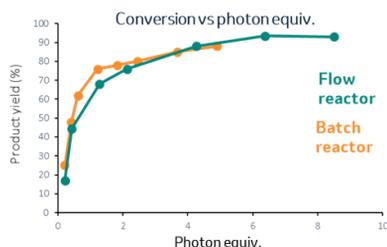
Photon stoichiometry: a key parameter across scales

- Demonstrated photon equivalents as the scaling factor

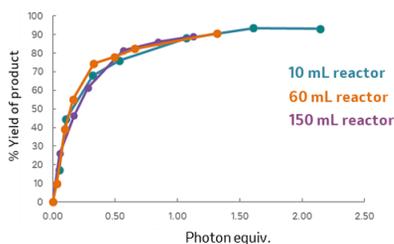
$$\text{Photon equiv.} = \frac{\text{moles of photons}}{\text{moles of S.M.}}$$



LED power & efficiency



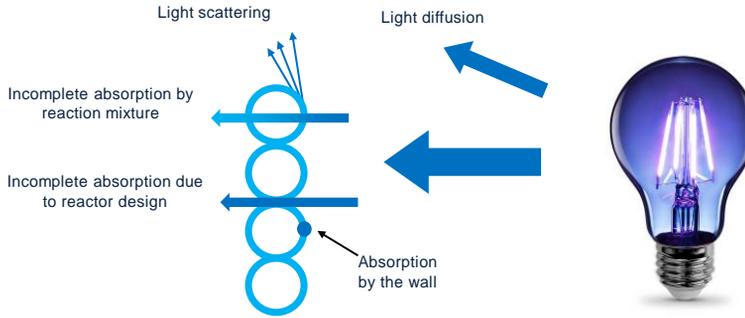
Scale-up



40

Reactor characterization

Not all photons from the light source enter the reactor or interact with the photocatalyst!



Due to similarities of reactor design and light source, emitted photons was used to estimate reaction time



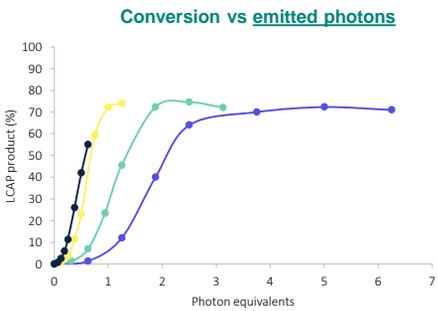
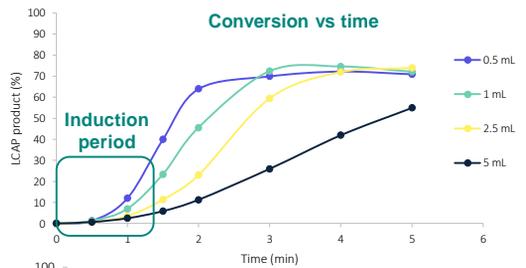
Photochemical bromination – Photon stoichiometry



0.5 mL, 1 mL, 2.5 mL, 5 mL



Foil = light absorption from bottom



Absorbing species is formed during reaction (induction period):
Abs changes over time!

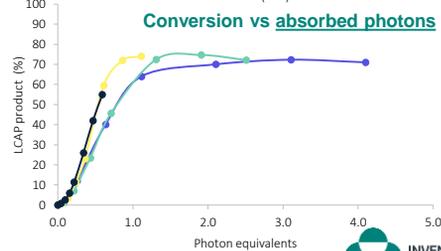
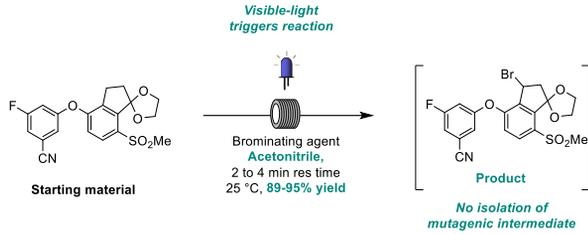


Photo-flow bromination



Photochemical initiation
Merck process



Higher end of reaction stability

Improved control in continuous-flow

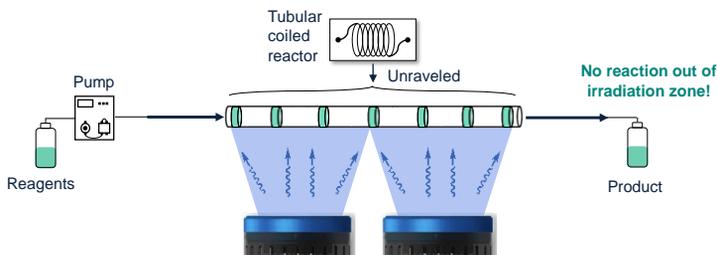


Photo-flow
selected as
manufacturing route

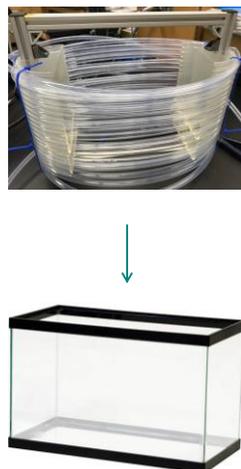


First kilo scale demonstration

Light source



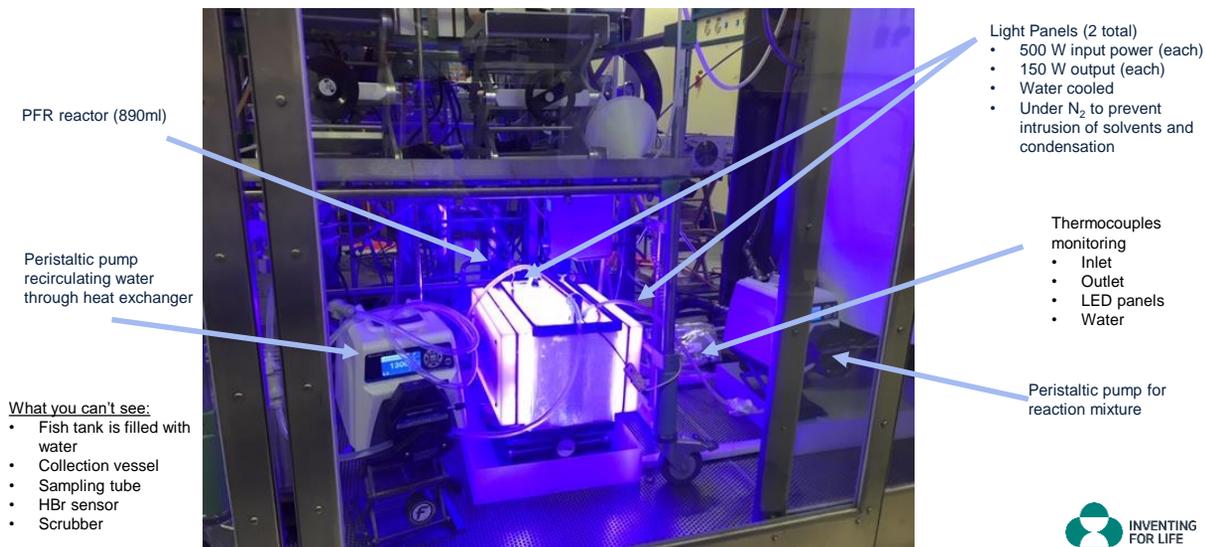
Reactor build



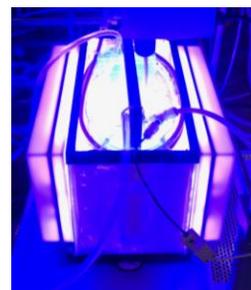
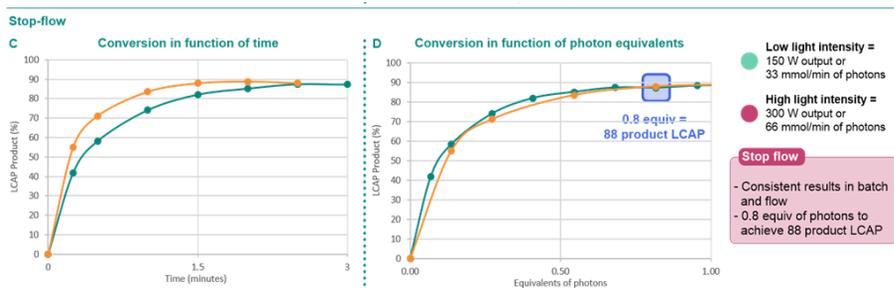
Small but mighty!



Photochemical bromination – Plug Flow Reactor



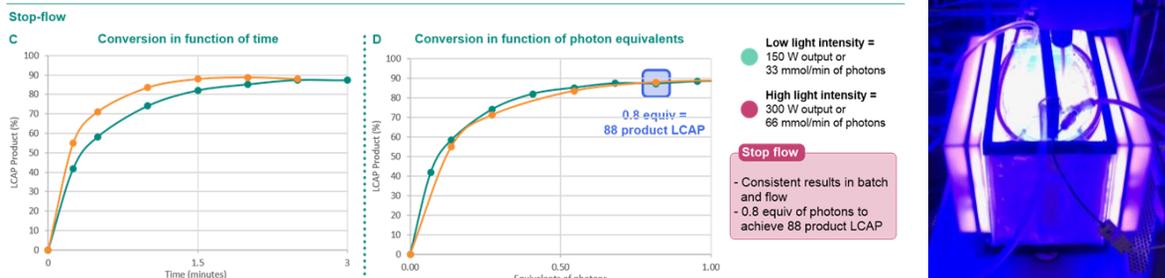
Reactor Characterization – Stop Flow Approach



No background reaction is observed in the absence of light.

Reactor was emptied and the reaction mixture was mixed prior to each illumination period.

Reactor Characterization – Stop Flow Approach



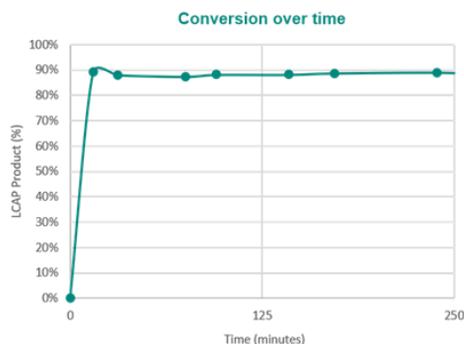
By using a stop flow approach, we were able to generate reaction profile with 1 L (50g SM) of stock solution.

Collecting the same data at steady state for each conditions would have required 21 L (>1kg SM) !



47

Scale-Up in Flow



Results overview

- 88 Product LCAP, 94% AY
- 0.2% SM, 2.05% gem-dibromo
- 3.75 min residence time
- 300 W power output
- Total run time 5h 57 min
- 3.5 kg of SM converted
- **Productivity 17 kg/day**

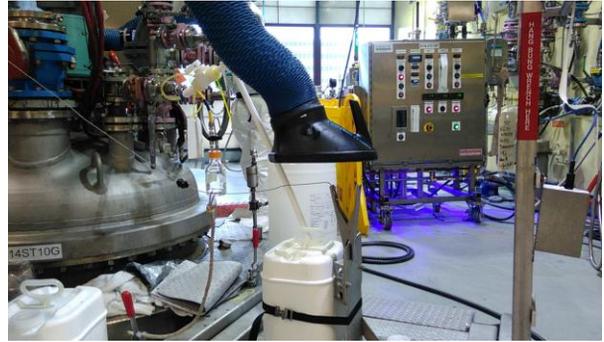
Good agreement between the stop flow and continuous flow.



48

Scaling up to the pilot plant

Working closely with pilot plant staff and external capabilities colleagues, a modular photoreactor skid with tunable LED power was developed which interfaced well with existing batch equipment.



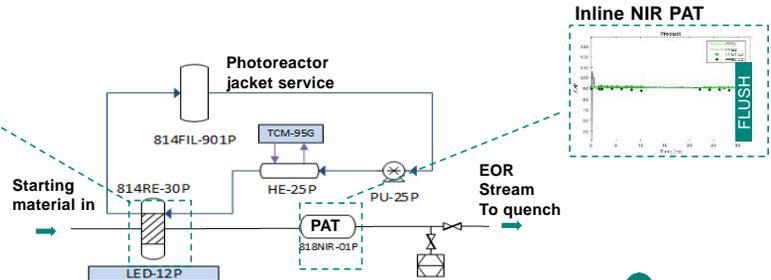
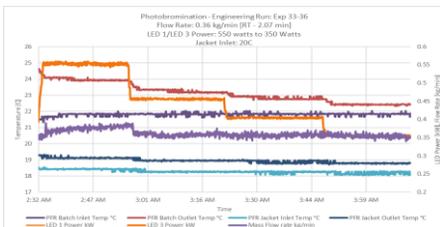
Production scale system – generating kilos and knowledge

- Pilot unit was designed with data-rich experimentation in mind
- Engineering batch explored ~80 different operating conditions.

Engineering Design Space

Factor	Lower Bound	Upper Bound
Time (min)	1	3
Power (W)	1000	1600
Temperature (°C)	15	35

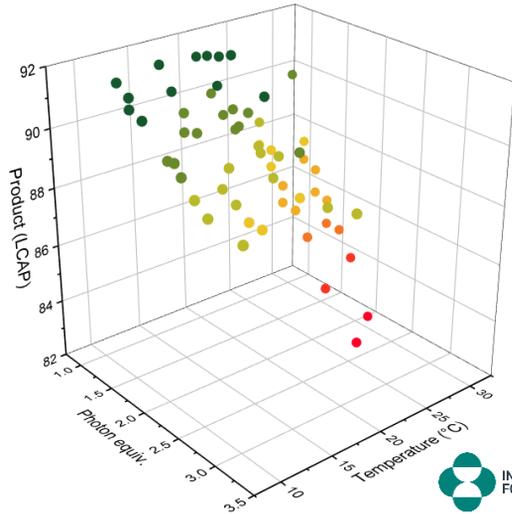
Sensors to monitor temperature, flow, pressure



Pilot plant results

Engineering Design Space

- Demonstrated quality of material maintained over wide range of conditions
- Verified photon equivalence as scale up factor
- Identified conditions for pilot plant batches (2 x 50 kg each)



51

Pilot plant campaign in Rahway



First photochemical reaction in our pilot plant



3x multi-kg batches, average 93% product yield



Productivity of 38 kg/day



Wide range of robustness conditions identified



52

API and Process qualification campaigns



Manufacturing train: 8 units in series



GMP-qualified



Productivity of 149 kg/day

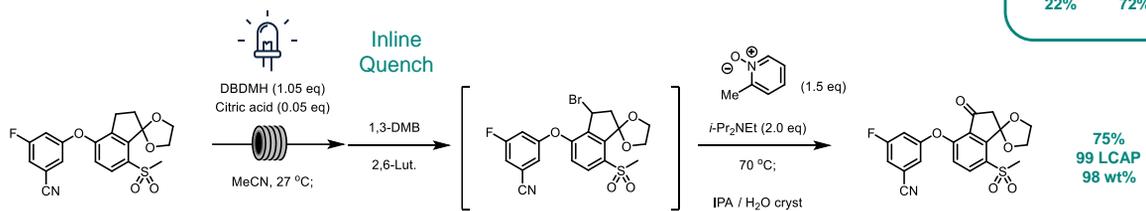


> 1 MT produced, > 94% average yield



53

Bromination / Oxidation – The Solution



- Robust & Reproducible
- HTHM -> Light!
- Non-chlorinated solvent

Stable stream
No Isolation

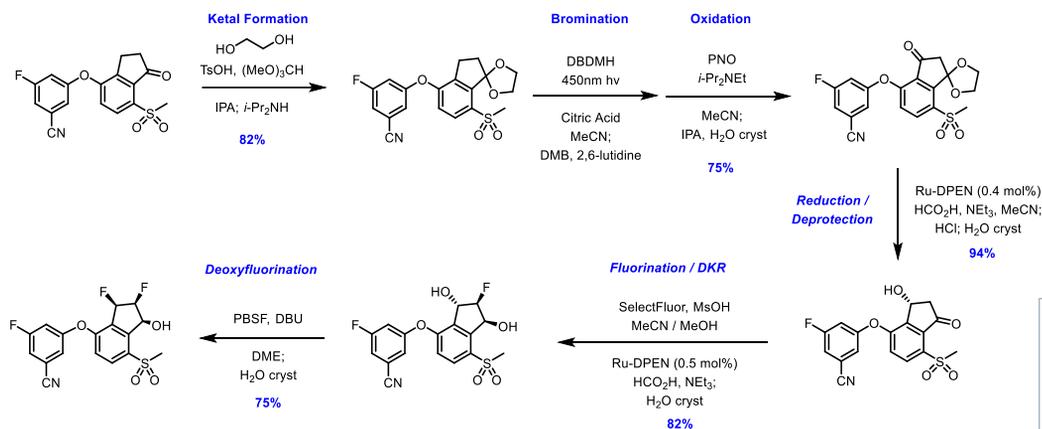
- Intrinsically Safe
- Benign oxidant - No Stench
- Direct crystallization

- Single solvent through process with direct isolation
- Robust and safe to operate with no stench
- Removed 2 x aqueous workups

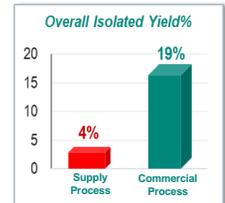
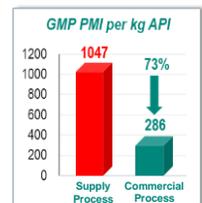


54

Delivering a Greener Commercial Process – GMP Pocket

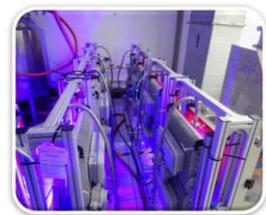


- Single solvent through-processes with direct isolations for all steps – no aqueous workups!
- 5/6 steps using MeCN – solvent recycling at commercial vendor
- Significant efficiency gains & waste reduction

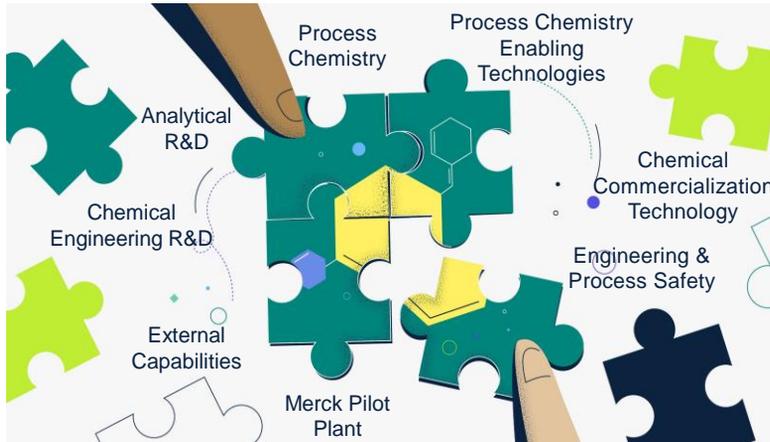


Conclusions

- Significant PMI reduction and sustainability gains for belzutifan process
- First photo-flow process for commercial manufacturing at Merck
- Capability established for future more efficient, robust and greener processes
- Keys to delivering on Green & Sustainable goals
 - Problem solving through best science
 - Risk-taking to innovate on critical path
 - Pre-investment in future technologies



Collaboration – On Behalf of the Merck Team



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Enabling Greener Pharma Manufacturing

Scaling a Photo-Flow Bromination for Belzutifan



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La Generación de Combustibles Solares Mediante Procesos Fotoinducidos

Fecha: Miércoles, 18 de Agosto, 2021 @ 2-3pm ET

Ponente: Dra. Leticia Myriam Torres Guerra, Centro de Investigación en Materiales Avanzados S.C. (CIMA)

Moderadora: Dra. María del Jesús Rosales Hoz, Cinvestav y Sociedad Química de México

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Lo Que El Público Aprenderá:

- Procesos de fotoconversión del agua en H_2 y O_2 y en la reducción fotocatalítica del CO_2
- Influencia del método de síntesis de óxidos cerámicos y variaciones cristaloquímicas de estos materiales en la eficiencia fotocatalítica de estos procesos
- El uso de un co-actulizador para mejorar el transporte de cargas y lograr una mayor actividad fotocatalítica

Co-producido con: Sociedad Química de México y *Chemical & Engineering News*



Date: Tuesday, August 31, 2021 @ 1-2pm ET

Speakers: Bill Carroll, Carroll Applied Science / Isiah Warner, Louisiana State University / Rajendran Mukhopadhyay, ACS Office of DEIR / Trinity Horton Hale, Celanese

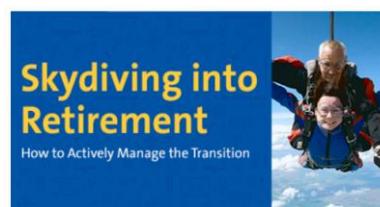
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62



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