



The e-newsletter for the Indian Biotech industry

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Biological drugs exports need urgent government attention



India's biotechnology companies demonstrated their manufacturing prowess for a variety of products urgently needed for the country and many parts of the world during the Covid years. Impressed by the country's capabilities, orders are pouring in from many parts of the world to manufacture a host of biological products to ABLE's member companies.

Our companies are not in a position to quickly respond to these orders due to some obstacles in the current regulatory processed related to export of such products from the country. Our companies possess the

capability to manufacture for purely export even some of the biological products that are new and not currently approved for use in the country or in the process of seeking regulatory approval.

In recent interactions with officials of Commerce and other ministries that are pushing to achieve the Prime Minister's vision of India achieving \$100 billion from only biological manufacturing services, ABLE has been requesting for a quick change in the current process. ABLE has requested government agencies to issue a one-time No Objection Certificate (NOC) /manufacturing license followed by Certificate for Pharmaceutical Product (COPP) for pharmaceutical and biological products that fall under unapproved/banned drugs/new drugs cattery solely for "export purpose" instead of current "country specific and quantity specific" approvals.

Our member companies say that such one-time manufacturing license will shorten the exports process from the current 8 to 10 months to just 2 months and will provide a big boost to India's BioEconomy and establish our country as a reliable, efficient exporter of biological drugs. Most of these export enquiries are for products approved in other countries and will be a great economic opportunity to showcase our capabilities to the world.

I am also happy to announce that ABLE has a taken a new initiative to help the industry's constant demand to have young employees ready to be recruited and deployed in their companies without having to spend too much time to get them ready for the jobs. **Kewaunee Labway India**, Patron Gold Member and **Aragen Life Sciences** together in partnership with **CSIR- Indian Institute of Chemical Technology (CSIR-IICT)** and **ABLE** have launched a **Biotech Finishing School Program** on July 4th at IICT that aims to provide hands-on practical training to postgraduate students in analytical chemistry and make them job ready especially in CRO/CDMO companies.

ABLE is supporting the program and had reached out to its network of academic institutes and faculty on their behalf. We have got a very good response and the screening of candidates who have applied is underway. The first batch of 20-25 candidates will be starting their training from the first week of August 2023. There will be many more batches of this excellent training program and I request all the biotech educational institutions to share the information about this initiative with their students so that they can benefit from it.

G S Krishnan President, ABLE

Launch of Industry supported Finishing School Program by CSIR - IICT

IN THIS ISSUE

- Launch of Industry supported Finishing School Program by CSIR – IICT
- ABLE curated Biopharma sessions at IPHEX 2023, 5-7 July, Hyderabad
- Serum Institute gets Govt award for Pneumococcal vaccine
- ABLE member Syngene acquires facility from Stelis Biopharma for ₹ 702 cr
- Interview with new Managing Director of BIRAC Dr Jitendra Kumar
- NCBS launches
 Rohini Nilekani
 Centre for Brain
 and Mind for
 research on
 severe mental
 illnesses
- Dr Anandkumar of Bugworks wins BioSpectrum Entrepreneur Award
- Aurobindo
 Pharma arm
 enters into
 license
 agreement with
 US company;
 shares fall









- ABLE signs MoU with YES Bank
- ABLE as
 Principal
 Knowledge and
 Association
 Partner for India
 Vaccines leaders
 Conclave
- Upcoming ABLE Webinar
- BIO 2024, San Diego, USA

CSIR-Indian Institute of Chemical Technology (CSIR-IICT), Aragen Life Sciences and Kewaunee Labway India Pvt. Ltd., together on 4th July 2023 formally launched a Finishing School program that will provide theoretical and practical training to postgraduate students in analytical chemistry as per the industry vetted course curriculum, The launch program saw the presence of Dr. Srinivasa Reddy, Director, CSIR-IICT, Mr. Sachin Dharap, CFO, Aragen, Mr. Sathyamurthy, Managing Director, Kewaunee Labway India, Mr. G.S. Krishnan, President, ABLE, Dr. D. Shailaja, Chief Scientist & Chief Scientist & Chair, Business Development & Research Management, CSIR-IICT, Dr. S. Balasubramnaya, General Manager, ABLE, senior scientists from CSIR – IICT, senior executives from both Aragen and Kewaunee Labway India.

The program supported by ABLE aims to make the students employable when they complete the training program successfully and assures them of internships or placements in the leading Pharma/Biopharma/CRO/CDMO companies. The industry-supported Finishing School Program will have 4 months of training followed by an internship or on-the-job roles of Advanced Organic Chemist & Advanced Analytical Chemist as per the National Skill Qualification Framework by utilizing the expertise and infrastructure of CSIR-IICT. The salient features of the program are as follows:

The training duration will be 4 months with more Hands-on exposure.

The trainee shall be equipped with all the skills that match the levels of a Senior Research Fellow.

A maximum of 30 participants will be trained in a batch.

The training fee fixed is Rs. 50,000 /- inclusive of GST per candidate, including accommodation on the campus. This training fee is highly subsidized by the participating industries.

All participating students will be issued a participation certificate on successful completion of the program.

The call for applications for the first batch is open and **CLICK HERE** to apply online.

ABLE curated Biopharma and Vaccines sessions at IPHEX 2023

5^t –7th July, Hitex Exhibition Centre, Hyderabad.

ABLE the permanent member of Committee of Administration of Pharmaceuticals Export Promotion Council of India (Pharmexcil) got an opportunity to curate two important sessions on Biopharmaceuticals and Vaccines at International Exhibition for Pharma and Healthcare (https://iphex-india.com/) on 6th July 2023 at Hitex Exhibition Centre, Hyderabad.



The 'Biopharmaceuticals' session moderated by Dr. P.M. Murali, President, Council of Presidents had the panelists in Dr. Subhra Ranjan Chakarabarti, Director - Operations, BIRAC, Mr. Nitish Kumar, Head of Customer Applications, Downstream, India, Merck Life Sciences and Dr. Jugnu

Jain, CEO, Sapien Biosciences. The panel discussed regarding the urgency for capacity building and expanding the scope of the National Biopharma Mission to make Bio manufacturing a \$100 B in India by 2025 and double it by 2030.



The session on 'Vaccines' also moderated by Dr. P.M. Murali, President, Council of Presidents had insightful discussion on recent developments in the Vaccine Industry, need to invest more in vaccine R&D and the roles of various stakeholders. The panelist included Dr. G.V.J.A

Harshavardhan, Viral Vaccines & International Afairs, Bharat Biotech & Secretary, Indian Vaccine Manufacturers Association, Dr. Vinod Pantula, Head - Vaccine Development, Dr. Reddys Laboratories, Mr. Atin Tomar, Co-Founder & CEO, Yapan Bio and Mr. Brij B. Baluni, Senior General Manager – Manufacturing, Zyduslife.

The recording of the both the sessions are available HERE.

ABLE signs MoU with YES Bank





ABLE and YES Bank have signed a Memorandum of understanding (MOU) to establish a non-binding collaboration aimed at creating an ecosystem for startups to help them scale, mentor and raise funds by introducing them to relevant mentors, angel investors, venture capitalists, ecosystem partners, banks and provide financial support for their growth.



From Left to Right: Mr Suresh TN (Regional Head for Retail Trade and Fx_Karnataka); Mr Roshan Thomas (Ecosystem Banking_ Karnataka, YES Bank); Mr Ritesh Verma (Zonal Head RTFx and CMS, YES Bank); Dr Balasubramanya S (General Manager, ABLE); Ms Indrila Sengupta (Asst. Manager – Business Development & Operations); Mr Shailendra Singhvi (Cluster Product sales manager RTFx, YES Bank); Mr Anirban Patra (Alliances and Intermediaries Management, YES Bank).

ABLE as Principal Knowledge and Association Partner for India Vaccines leaders Conclave

22nd-23rd August, Courtyard by Marriott, Mumbai



The 2nd Edition of the India Vaccine Leaders Conclave (IVLC 2023) is scheduled to take place on 22nd & 23rd August at Courtyard by Marriott, Mumbai along with the Biopharma Awards.

The IVLC strives to provide a meaningful theme of "Building Resilient Vaccine Ecosystems" & will assemble leading specialists and renowned experts and it also serves as a premier platform that brings together key stakeholders, industry experts, policymakers, and thought leaders in the field of vaccines. This event aims to foster collaborative discussions, share insights, and address critical challenges related to vaccine development, distribution, and public health strategies.

Early bird registration is open now. For more information visit the event website. For any queries, write to us at indrilas@ableindia.org.in



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FAQs

Who is eligible for this program?

Only Pharmacy, Biotech and Life-Sciences Teaching Faculty and PhD Students who are also teaching faculty are eligible to join this program.

What is the format of the training?

The training is provided live online and supported with the recorded sessions through our Learning Management System (LMS).

How can I learn programming as I am from Pharmacy background?

Our experienced professionals who teach programming are Pharmacists and data used to teach programming is also pharma data. You will be taught from scratch and access to recorded sessions is provided for practice.

You will have the power of an EdTech Company

As a Certified Trainer you can offer to your students:

- Existing Recorded sessions on our LMS without taking trouble to create new
- Conduct Exams
- · Provide Certification
- · Customer Service by SkillYaari
- Placement Assistance by LSSSDC
- You can charge how much ever you want from your students as a Freelancer
- Per student you can pay just 3,500 as administrative charges to provide all the above benefits to the student.

Get Listed with us We will help you Earn!

Get listed as a Certified Trainer on Portal:

- You can share Existing Recorded sessions on our LMS without taking trouble to create new to the students.
- Conduct Exams
- Provide Certification
- Customer Service by SkillYaari
- Placement Assistance by LSSSDC
- The standard charges for each course is around 15,000 INR to 25,000 INR only and the fee is fixed by the company to increase registrations.
- Company will deduct 3,500 INR from the fee and transfer the remaining amount into your account.

How will I get the certification?

You can learn one or all the courses during this one year or learn the courses required by you for the paid assignments. After each program you will have to clear the certification exam or required projects to receive certification.

How can I use this program to earn?
This program is to empower the
Pharmacy Faculty only. Pharmacy
faculty can use this in three different
ways to earn:

- Complete the course you like and take our paid assignments to earn.
- Take a paid teaching assignment from students and then complete the course using our LMS.
- As a certified trainer you can provide our recorded sessions to your paid students, certifications including LSSSDC Certification.

Program Fee:

20,000 INR*

12 Month Zero Interest Student Loan Available





Call: 9392339218, 7013201220

Upcoming ABLE Webinar

"Innovations in Clinical Research and Data Management: Empowering Lifesciences and Biotechnology Faculty"

In this webinar, we will explore the latest trends and innovative techniques in clinical research and data management, specifically tailored for faculty members from the fields of Lifesciences and Biotechnology. As the landscape of research methodologies evolves rapidly, it is crucial for educators and researchers to stay updated with the newest advancements and best practices in the field.

By attending this webinar, faculty members and researchers will gain valuable insights and practical knowledge to elevate their teaching methods, enhance research practices, and drive impactful contributions to the ever-evolving fields of Lifesciences and Biotechnology.

Stay Tuned!

BIO 2024, San Diego, USA

Special Early Bird Offer for Booking Exhibition Booth Space in India Pavilion





BIO 2024, the BIO International Convention & Exhibition, will take place from 3-6 June 2024 in San Diego, CA, USA. It is the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world. BIO presents a great opportunity for India's biotech companies, startups, incubators,

to build key relationships, partnerships, and channels for extending businesses.

ABLE and its member companies have been participating in the convention since 2005. And since 2012, ABLE has been handling the India Pavilion with support from the Department of Biotechnology (DBT) and the Biotechnology Industry Research Assistance Council (BIRAC).

We are happy to announce that ABLE is organizing the India Pavilion yet again at BIO San Diego with a total space of 1500 SQF. A high-level Indian delegation comprising senior Government officers from the Centre and State, CEOs of leading Biotech companies, Academic Heads, and Startups, are expected to participate. We invite organizations from the Government, Public Sector, and Private (Startups, SMEs & larger companies), to participate as Exhibitors in the India Pavilion and reach out to the Global market.

For more information please **Click Here** Or contact Dr Balasubramanya S (gm@ableindia.org.in)

Serum Institute gets Government of India award for Pneumococcal vaccine



ABLE Patron Gold Member, Serum Institute of India, was given the Government of India's 'GeM Gaurav Samman' for excellent EPI business of its Pneumococcal Conjugate Vaccine (PCV).

The award was presented by Mrs Anupriya Patel, Union Minister of State - Commerce & Industry to SII Director - Government & Regulatory Affairs Mr. Prakash Kumar Singh at the 'Kreta-Vikreta Gaurav Samman Samaroh 2023' function held at Vanijya Bhawan, New Delhi in June 2023.

Government e-Marketplace (GeM) is the National Public Procurement Portal for procurement of goods and services for Central and State Government Organisations. GeM organized the 'Kreta-Vikreta Gaurav Samman Samaroh 2023' to recognize the outstanding performance of government buyers and sellers in the public procurement process through GeM. The buyer-seller award ceremony is an initiative by GeM to acknowledge the efforts of government buyers and sellers who have performed exceptionally well in using the platform for the procurement process in FY 22-23.

ABLE member Syngene acquires facility from Stelis Biopharma for ₹ 702 cr



Syngene International, a subsidiary of Biocon Ltd., has decided to acquire a Unit 3 biologics manufacturing facility in Bengaluru from Stelis Biopharma Limited (SBL) on a slump sale basis for a gross value of ₹702 crore.

The deal, which is expected to close in 90 days, would include a commercial scale, high-speed, fill-finish unit--an essential capability for drug product manufacturing. The facility has the potential for future expansion of up to a further 20,000 liters of biologics drug substance manufacturing capacity, the company said in a statement.

The facility, which was initially built to manufacture Covid-19 vaccines, is now being repurposed to manufacture monoclonal antibodies and Syngene will further invest up to ₹100 crore to revalidate the facility, as per the company.

"This acquisition strengthens our growing position as a leading biologics contract development and manufacturing service provider and adds drug substance capacity and a drug product capability years earlier than our internal capex programme," Jonathan Hunt, Managing Director and CEO, Syngene International said.

There was healthy demand for high quality biologics manufacturing capacity from sectors ranging from large pharma to emerging biotech companies, he further said. "We expect this new facility to be operational in 2024, following completion of a programme of facility upgrades and re-validation."

Source: The Hindu

Interview with new Managing Director of BIRAC Dr Jitendra Kumar

"New bioincubators would be set up to cater to the growth of startup ecosystem including the tier 2, tier 3 regions"



Dr Jitendra Kumar, the former Director of Bangalore Bioinnovation Centre (BBC), has taken charge as the new Managing Director (MD) of Biotechnology Industry Research Assistance Council (BIRAC), an institution set up by the Department of Biotechnology (DBT), Government of India, to nurture and promote biotechnology innovations and industry in India.

In an exclusive interview with BioSpectrum, Dr Jitendra Kumar, MD, BIRAC lays bare his new vision and strategies for the growth of the biotech sector.

1. What unique strategies are you planning to implement as the MD of BIRAC?

A major challenge faced by startups in India is the inability to scale up. We need to develop multiple centres for startups to be able to manufacture and initiate trials at large scale. So, my vision would be to facilitate scaling up of startups by setting up at least five such centres. There is also a need to establish a platform where big companies can interact with startups. BIRAC can provide such a platform to the startups where extensive interactions can take place. Industry can strategically tie up with startups to ensure the success of an idea. For instance, in the case of new drug discovery, a startup can conduct pre-clinical trials, and once successful, the technology can be translated to an industry partner to strategically bring the drug faster to the market after conducting the necessary clinical trials. Although startups might have apprehensions to undergo such strategic partnerships with big industry players, BIRAC can play a critical role in easing out the path for both startups and big companies.

2. Are there plans to open more bioincubators in the country to strengthen the ecosystem for biotech startups in India?

New bioincubators would be set up to cater to the growth of the ecosystem including the tier 2, tier 3 regions. BIRAC would also partner with some of the progressive states and run state level programmes for the startup. For instance, Bangalore Bioinnovation Centre is the only bioincubation centre jointly run by the central and state government. There is a need to create similar models in the country so that all the resources can be pooled together and the required funding can be accommodated for the growth of these startups. At present, many incubation centres are running on project modes. In addition, BIRAC also has plans to lay emphasis on developing new policy norms for the regulatory hurdles being encountered by startups across the country, particularly those working on new emerging technologies.

3. The government's vision is to increase the number of biotech startups from 5000 to 50,000 in the coming years. What is your opinion?

Currently, the scenario is that we are waiting for startups to come up to gradually increase in number. But this is not a sustainable way forward. A more robust way to gradually increase the number of biotech startups in our country would be to adopt institutional mechanisms where we can have dedicated programmes within the academic institutes to commercialise those technologies that are lying on the shelf, with support, funding and incubation from BIRAC. We can, thereby, create a whole database of such technologies that are available with the academic institutes to be picked up by the students who can become the future entrepreneurs. The institutional mechanisms could also create ventures and it can emerge as an evolutionary process for the growth of biotech startups. In addition, we need to showcase the success stories as more startups are able to scale up and commercialise their innovation.

Source: Biospectrum India

NCBS launches Rohini Nilekani Centre for Brain and Mind for research on severe mental illnesses

Rohini Nilekani, chairperson of Rohini Nilekani Philanthropies, unveiled the plaque to mark the inauguration of the centre on the NCBS campus. In May this year, Rohini Nilekani Philanthropies announced the grant of Rs 100 crore to the NCBS and the National Institute of Mental Health and Neurosciences (NIMHANS) to set up the centre.

The National Centre for Biological Sciences (NCBS), Bengaluru Tuesday announced the launch of the Rohini Nilekani Centre for Brain and Mind, a centre dedicated to advancing research and practice pertaining to neurodevelopmental disorders and mental health. The centre will focus on the long-term examination of environmental and genetic factors involved in brain development which underlie severe mental illnesses.

Rohini Nilekani, chairperson of Rohini Nilekani Philanthropies, unveiled the plaque to mark the inauguration of the centre on the NCBS campus. In May this year, Rohini Nilekani Philanthropies announced the grant of Rs 100 crore to the NCBS and the National Institute of Mental Health and Neurosciences (NIMHANS) to set up the centre.

"The centre will support research through its partnership with the National Institute of Mental Health and Neurosciences (NIMHANS) and NCBS' therapeutic practices pertaining to five mental disorders: schizophrenia, bipolar disorder, addiction, obsessive-compulsive disorder, and dementia – conditions considered neurodevelopmental in origin. The research work of the centre will combine the molecular biological research capabilities and technologies at NCBS with the stem cell capabilities established at the Institute for Stem Cell Science and Regenerative Medicine (inStem-DBT), an autonomous institution under the Department of Biotechnology, Government of India. inStem has been and will continue to

partner with NCBS on research activities, including that of the Accelerator program for Discovery in Brain disorders using Stem cells (ADBS)," the NCBS said in a release. Speaking about the centre, Rohini Nilekani said, "India has a significant number of people, around 193 million, dealing with mental illness. The proportional contribution of mental disorders to the total disease burden in India had almost doubled since 1990, and this calls for urgent attention. The Centre for Brain and Mind will attempt to address this challenge by driving interdisciplinary research to understand the complexities of brain and mind conditions. More Research originating from India is critical at this juncture. The collaboration between NCBS and NIMHANS will provide globally relevant insights, evidence and pathways for better treatment for millions of people in India and the world. I hope medical practitioners, decision-makers and researchers will join the community and co-create success for this endeavour."



Talking about the centre, Prof L S Shashidhara, Director, NCBS, said, "Improvements in human health and well-being have often been possible through the development of new technologies and their application to finding solutions for medical problems. We are at an opportune moment where recent advances in genomics, cell biology and stem cell technology offer an exciting opportunity for discovery science that can be applied to the problems of human mental illness. With the generous support of Rohini Nilekani Philanthropies (RNP), NCBS looks forward to working with NIMHANS and other partners at 'the Center for Brain and Mind' to develop new solutions for the early diagnosis and better clinical management of mental illness."

Commenting on the centre, Dr Pratima Murthy, Director, NIMHANS, said, "It is a greater challenge to get research support for mental health as compared to physical disorders like cancer. NIMHANS, along with NCBS, has been carrying out research looking at shared and unique markers in severe mental illness. The generous funding provided by the Rohini Nilekani Philanthropies to NIMHANS and NCBS in order to establish 'the Centre for Brain and Mind' at both institutions is a great opportunity to further this research. This will enable us to look further into the common as well as distinctive biological (including genetic) and psychosocial underpinnings of disorders such as schizophrenia, bipolar mood disorders, obsessive-compulsive disorders, addictive disorders and dementia."

Source: The Indian Express

Dr Anandkumar of Bugworks wins BioSpectrum Entrepreneur Award



Anand Anandkumar, co-founder of Bugworks Research and Vice President & Treasurer of ABLE was given the Entrepreneur of the Year by biotech industry magazine, BioSpectrum. The BioSpectrum Excellence Awards for 2021-22 were presented in New Delhi on June 30, 2023.

The other winners were:

- Businessperson of the Year Mahima Datla, Managing Director, Biological E
- Woman Entrepreneur of the Year Geethanjali Radhakrishnan, Founder, Adiuvo Diagnostics
- Product of the Year SSI Mantra Surgical Robotic System by SS Innovations
- Young Woman Scientist of the Year- Dr Pragya D Yadav, Scientist-F, National Institute
 of Virology

The awardees were chosen by a jury headed by Dr Renu Swarup, former secretary, Department of Biotechnology (DBT), Government of India. This is the 13th edition of the annual BioSpectrum since the magazine was founded in 2003.

Dr K I Varaprasad Reddy, non-executive chairman of Shantha Biotechniques was given the Life Time Achievement Award Year 2021-22.

About the BioSpecrum Excellence Awards 2023, Mr Ravindra Boratkar, Publisher and Managing Editor, BioSpectrum India, MM Activ Sci-Tech Communications, said "India's bioeconomy is poised to touch \$300 billion by 2030 and with its rising innovation and scientific temper, India is set to join the global wave of a new industrial revolution. India is emerging as the world's major bioeconomy with fast growing biotech startups. The number of biotech startups has increased from 50 to 5,000 in the last 8 years. India has the potential

Dr

to move from 5,000 to 50,000 within the biotech startup sector. Considering this growth, BioSpectrum also wants to be part of this growth journey of the Bio & Health Sciences startup ecosystem and contribute in different aspects like skill development, mentoring, investments to take it to the next level. We are launching MMA Spectrum Foundation to become a partner of this progress of Bio & Health Sciences startups ecosystem."

In her address, Dr Renu Swarup congratulated all the award winners for their performance and achievements, and complemented BioSpectrum for its efforts in bringing the hidden jewels into the limelight. "These efforts of BioSpectrum are going to help the young students of biotechnology see these winners as role models. As the country is offering huge opportunities in the biosciences space, the young minds can grab these through their skill sets and talent to make a difference to the society", she said.

Accepting the Life Time Achievement Award, Dr Varaprasad Reddy recalled his tough and solo journey of developing recombinant DNA vaccines with a motto of offering them at an affordable price three decades ago. "We have great doctors, great engineers in our country but not great leaders. The vaccine scenario has changed considerably in India. Currently, we are strong in production but we should collaborate with other countries for joint development and own the patent rights, to become global leaders."

Aurobindo Pharma arm enters into license agreement with US company; shares fall

Under the terms of the agreement, CuraTeQ has been granted exclusive license rights to commercialise BFI-751 in all major regulated markets, certain semiregulated, and emerging markets worldwide.

The company has 24 manufacturing and packaging facilities that are approved by leading regulatory agencies including USFDA, UK MHRA, EDQM, Japan PMDA, WHO, Health Canada, South Africa MCC, Brazil ANVISA.



Aurobindo Pharma share price erased opening gains and turned red on July 10 as its wholly owned subsidiary CuraTeQ Biologics announced that it has entered into an exclusive license agreement with the United States-based BioFactura to commercialise an antibody used to treat many digestive and skin

ailments.

The share touched a 52-week high of Rs 765 and a 52-week low of Rs 397.30 on 06 July, 2023 and 03 February, 2023, respectively. Currently, the stock is trading 4.33 percent below its 52-week high and 84.22 percent above its 52-week low. BFI-751, is a proposed biosimilar to Stelara (Ustekinumab). Ustekinumab is a recombinant monoclonal antibody that works by blocking both interleukins IL-12 and IL-23 and is used for treating Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis.



ASSOCIATION OF BIOTECHNOLOGY LED ENTERPRISES (ABLE)

Comments and questions are welcome and should be addressed to:

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