BioPharma India 2016

15-16 NOVEMBER 2016
MUMBAI, INDIA

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Mr. Subhra Ranjan Chaktrabarti, Associate Vice President**, Shantha Biotechnics (a Sanofi Company)**

CONFIRMED SPEAKERS

1. **Alap Gandhi,** Head, Medical Affairs, **GSK**
2. **Alok Sharma,** Principal Scientist and Head, Analytical Development Lab, Biotech Division, **Lupin Limited**
3. **Ankur Bhatnagar,** Associate Director, **Biocon**
4. **Arnab Kapat,** Director, Reliance Institute of Life Sciences and Vice President, **Reliance Life Sciences**
5. **Atin Tomar**, President, **CPL Biologicals**
6. **B N Manohar,** CEO & MD, **Stempeutics**
7. **Barbara Paldus,** CEO**, Finesse**
8. **Chandru Chawla,** Head of Corporate Strategy and New Ventures, **Cipla**
9. **Davinder Gill,** CEO, **MSD Wellcome Trust Hilleman Labs**
10. **Dhaval Trivedi,** Assistance Vice President, Regulatory Affairs, **Stelis Biopharma (Strides Shasun Entreprise)**
11. **G S Reddy,** Chief General Manager, Manufacturing, **Indian Immunologicals Limited**
12. **Hanmant Barkate,** Vice President & Head, Medical Affairs, Clinical Development and Regulatory Affairs, **Intas Pharmaceuticals**
13. **Harish Shandilya,** Senior General Manager, **Enzene Biosciences, part of Alkem Laboratories**
14. **Kaushik Deb,** Founding Director, **DiponEd BioIntelligence**
15. **Madhavan Nampoothiri,** Principal Scientist and Head, Biotechnology Division, **CSIR-NIIST**
16. **Manoj Kumar,** Director, R&D, **MSD Wellcome Trust Hilleman Labs**
17. **Mayur Sirdesai,** Director, **Somerset Indus Capital Partners**
18. **Natasha Shanker,** Associate Director, Quality Control **Dr Reddy's Laboratories**
19. **Nirav Desai,** Vice President, **CPL Biologicals**
20. **Pazhanimuthu Annamalai,** Managing Director**, AuraBiotech**
21. **Praveen Duhan**, Associate Global Medical Director, Global Medical Affairs, **Novartis Healthcare**
22. **Rajendra Jani,** Senior Vice President, Clinical R&D, **Zydus Cadila**
23. **Rajesh Naik,** Head Medical Affairs Oncology, **Boehringer Ingelheim**
24. **Rajinder Kumar Suri**, Senior Advisor and Former Chief Executive Biologicals, **Panacea Biotech**
25. **Randy Hice,** Manager, Global Strategy**, Abbott Informatics**
26. **Ravishankar Kasturi,** Asst. Vice President and Head of Manufacturing & Process Development, **Reliance Life Sciences**
27. **Samir Kulkarni,** Associate VP & R&D, **Intas Pharmaceutical**
28. **Satyen Sanghavi,** Chief Scientific Officer, **Regrow**
29. **SD Sinha,** Vice President, Global Pharmacovigilance Clinical Development and Medical Affairs, **Hetero Drugs Ltd**
30. **Stefan Hart,** Director, New Ventures, **Johnson & Johnson**
31. **Subhadra Dravida**, Co-Founder and CEO, **Transcell**
32. **Subhra Ranjan Chaktrabarti,** Associate Vice President**, Shantha Biotechnics (a Sanofi Company)**
33. **Sudeep Singh Gadok,** Senior Vice President, Enterprise Development, **MSD Wellcome Trust Hilleman Labs**
34. **Sundar Kodiyalam,** Managing Director and Co-Founder, **Vatera Healthcare Partners**
35. **Supreet Deshpande,** CEO, **NovaLead Pharma**
36. **Venkateswarlu Nelabhotla**, Co-Founder & CEO, **Vyome Biosciences**
37. **Vijay Chandru,** Executive Chairman, **Strand Life Sciences**
38. **Vikram Paradkar,** Senior Vice President, Technical Operations, **Biological E**
39. **Kedar Nayak,** Area Manager, In-Country Clinical Operations, India, Russia, Middle East, Africa, **GSK**
40. **Ross Acucena,** Product Strategy Manager - Bio Process, **Wipro-GE Healthcare**
41. **Dakshesh Mehta,** Associate Vice President, Head – Bioprocess Development, Biotech R&D, **Wockhardt**
42. **Sanjay Singh,** CEO**, Gennova Biopharmaceuticals**
43. **Surya Pai,** Founder and CEO**, Bhami Research Labs**
44. **Amit Varma,** Managing Partner, **Quadria Capital**

Confirmed
Pending

CONFERENCE DAY 1 OPENING KEYNOTE PLENARY: ENCOURAGING INNOVATION AND ENTREPRENEURSHIP		
08:50	**Organiser's opening remarks**	
08:55	**Chair's opening remarks**	
09:00	**Guest of honour keynote opening address** **Fostering biotechnology innovation and entrepreneurship in India - Where we are now & what's next?** India is the third largest biotechnology economy in the APAC region and the number 1 producer of Hepatitis B vaccines recombinant. As biotechnology brings solutions to the needs and problems of human society in the coming years, government support is paramount to the success of this industry. Join this session to find out how India's government is working to encourage biotechnology and entrepreneurship in India.	
09:30	**Making affordable, accessible, and thermo-stable vaccines in India** Due to insufficient cold chain infrastructure, providing essential vaccines to less accessible regions is a great challenge in India. To overcome this difficulty, researchers worked to create thermo-stable biological products to minimize the need of cold chain services in storage and transportation stages. Leading Hilleman Labs, a joint venture between MSD and WEllcome Trust, Dr Davinder Gill, its CEO Of Hilleman Labs shares their journey from development of thermo-stable, to finding the right manufacturing partner, and improving access to essential vaccines to prevention of diseases in India. **Davinder Gill,** CEO, **MSD Wellcome Trust Hilleman Labs**	
10:00	**Managing partnerships in joint-venture settings** Joint venture is among the popular choices in for-profit company to improve visibility and reach in global pharmaceutical industry. Representing CPL Biologicals as its newly appointed president, Atin joins us in this conference to share his view on the key strategies for him and his team in managing the different aspects of this India-USA joint venture in India. Key discussions include managing stakeholder relationship, creating melting pot in the organisation, recruiting and retaining talents and moving forward from status quo. **Atin Tomar**, President, **CPL Biologicals**	
10:30	Speed networking	
10:40	Networking Refreshment Break	
	THERAPEUTIC INNOVATION	**MANUFACTURING** **PROCESS DEVELOPMENT**
11:00	**Chair's opening remarks**	**Chair's opening remarks** **Barbara Paldus,** CEO**, Finesse, USA**
11:05	**Bridging the gap between research and commercialisation in the development of novel bacterial vaccines** • Understanding the major hurdles to bringing novel vaccines to commercialisation phase • Strategies for encouraging production of more 'commercialisable' and patentable innovations • Training and developing younger talents to instil use-inspired research **Manoj Kumar,** Director, R&D, **MSD Wellcome Trust Hilleman Labs**	**The role of bio-manufacturing plant automation in productivity enhancement, quality improvement and regulatory compliance** • Understanding automation in the bio-manufacturing context • Exploring productivity enhancement through the seamless automation of unit operations • Meeting international regulatory standards through automated solutions **Arnab Kapat,** Director, Reliance Institute of Life Sciences and Vice President, **Reliance Life Sciences**
11:25	**Bringing drugs targeting tuberculosis from the laboratory to the commercial phase**	**Building a seamless, smart production facility in India**

	• Discovering the latest tuberculosis research in India • Working with industry partners to make the next scientific breakthrough • Understanding the best partnership and discovery models for scientific communities in India **Madhavan Nampoothiri,** Principal Scientist and Head, Biotechnology Division, **CSIR-NIIST**	• Discovering strategies to overcome challenges in scaling up production values from lab to manufacturing • Exploring smart technologies available for effective manufacturing process design • Balancing the costs and benefits in implementing a smart factory in India **Barbara Paldus,** CEO**, Finesse**
11:45	**Overcoming quality issues in clinical development and research in India** • Meeting the challenges of fulfilling Indian clinical trial requirements • Exploring solutions to improve India's clinical trials results and quality • Improving clinical data with risk-based monitoring: A case study **Kedar Nayak,** Area Manager, In-Country Clinical Operations, India, Russia, Middle East, Africa, **GSK**	**Innovating vaccine manufacturing in India: Where are we now?** • Addressing the challenges imposed by regulatory restrictions on vaccine manufacturers • Overcoming the complexity of improving vaccine manufacturing processes to increase efficiency and reduce cost • Understanding the role of vaccine manufacturers in innovating processes to remain competitive in quality and product pricing **Subhra Ranjan Chaktrabarti,** Associate Vice President**, Shantha Biotechnics (a Sanofi Company)**
12:05	**Understanding the role of venture capital in duplicating India's generics success to NCE and biologics development** • Exposing Indian scientists and entrepreneurs to alternative funding and sources of capital for building a biotech in India • Building a successful biotech/specialty pharma company: A case study • What does it take to secure venture capital funding: Elements of a successful business plan **Sundar Kodiyalam,** Managing Director and Co-Founder, **Vatera Healthcare Partners**	**Streamlining R&D preparation to ensure successful technology transfer and process optimisation** • Investigating the role of R&D before transfer of process ownership • Establishing critical aspects which requires evaluation to ensure event free manufacturing operations • Communication and training required to prepare for successful technology transfer and manufacturing processes **Samir Kulkarni,** Associate VP & R&D, **Intas Pharmaceutical**
12:25	**Networking Lunch**	
	BIOTECH INNOVATION SHOWCASE	**UPSTREAM**
14:00	This exciting new addition to BioPharma India 2016 will see 8 of India's most exciting and innovative biotechs offering 10-minute insights into their products, pipelines and their pathway to commercialization. Join us and hear from the innovators at the forefront of India's biotech sector. **Chairman:** **Sundar Kodiyalam,** Managing Director and Co-Founder, **Vatera Healthcare Partners** **Biotech companies:** - **Satyen Sanghavi,** Chief Scientific Officer, **Regrow** - **B N Manohar,** CEO & MD, **Stempeutics** - **Subhadra Dravida**, Co-Founder and CEO, **Transcell**	**Managing multi-batch manufacturing: An upstream perspective** • Understanding the requirements for managing multi-batch upstream processes • Building scalable, flexible control platforms with multi-batch production tools • Using centralised plant management to avoid cross-contamination **Ravishankar Kasturi,** Assistant Vice President and Head of Manufacturing & Process Development, **Reliance Life Sciences**
14:20		**Developing a cell-based vaccine manufacturing process** • Exploring the potential for mass production of cell-based influenza vaccines • Strategies to generate mammalian cell lines for vaccine production

<table>
<tr><td></td><td rowspan="3">- Supreet Deshpande, CEO, NovaLead Pharma
- Vijay Chandru, Executive Chairman, Strand Life Sciences
- Vishwas D Joshi, Director, Seagull Biosolutions
- Venkateswarlu Nelabhotla, Co-Founder & CEO, Vyome Biosciences
- Surya Pai, Founder and CEO, Bhami Research Labs</td><td>• Balancing the cost and efficiency of cell vs egg based production
Senior representative, Merck</td></tr>
<tr><td>14:40</td><td>Improving cell density, productivity and scalability in antibody production
• Investigating the limitations of current antibody production methods
• Discovering how upstream perfusion helps to improve cell density and productivity
• Understanding how perfusion systems help to build flexibility in scaling production sizes
Ankur Bhatnagar, Associate Director, Biocon</td></tr>
<tr><td>15:00</td><td>How development of new generation single-use films can ensure optimal performance across the full bioprocess unit operation workflow
• Presenting the importance of resin selection and film architecture on achieving critical to quality attributes for design of bioprocess film
• Discovering the importance of consistency, biocompatibility, chemically inert and low level extractable of single use system
Ross Acucena, Product Strategy Manager - Bio Process, Wipro-GE Healthcare</td></tr>
<tr><td>15:20</td><td colspan="2">Networking Refreshment Break</td></tr>
<tr><td>16:00</td><td colspan="2">Roundtable Discussion Session
Choose from our 8 roundtable discussions. Simply pick a table and join the debate.</td></tr>
</table>

Table 1: Building local and international partnerships **Stefan Hart,** Director, New Ventures, **Johnson & Johnson**	**Table 3:** Integrating continuous processing with existing biophamanufacturing facilities Senior Representative, **Thermo Fisher Scientific**	**Table 5:** Low cost, high quality biomanufacturing	**Table 7:** Improving novel cell lines to improve expression and quality
Table 2: How stakeholders can work together in building a sustainable innovation ecosystem in India? **Giridhar Sathiamoorthy,** Director, Business Operations and Project Management, **Johnson & Johnson** **Mayur Sirdesai,** Director, **Somerset Indus Capital Partners**	**Table 4:** Improving healthcare access in India **Sudeep Singh Gadok,** Senior Vice President, Enterprise Development, **MSD Wellcome Trust Hilleman Labs**	**Table 6:** Challenges and solutions in India's biocomparability studies	**Table 8:** Upscaling novel therapeutic products **Senior representative, Merck**

16:50	**BEERS & BIOTECHS NETWORKING SESSION** *Grab a beer and join us for this exciting session where 8 exciting new biotechs will have the opportunity to showcase their elevator pitch. Hear from some of India's hottest new biotech prospects whilst enjoying a drink – don't forget to bring your business cards!* **Kaushik Deb,** Founding Director, **DiponEd BioIntelligence** **Pazhanimuthu Annamalai,** Managing Director, **AuraBiotech**
17:10	**End of Conference Day 1**

<table>
<tr><th colspan="3">CONFERENCE DAY 2
KEYNOTE PLENARY: INDUSTRY OUTLOOK</th></tr>
<tr><td>08:50</td><td colspan="2">Chair’s opening remarks</td></tr>
<tr><td>09:00</td><td colspan="2">From Imitator to Innovator: How India can become the next international R&D destination from an API & generics manufacturing hub
With increasingly skilled and affordable labour, and a growing commitment to strengthening IPR and infrastructure within the country, India is now transforming itself from an API and generics manufacturer to an innovation-driven manufacturing hub. Find out how India can improve its infrastructure and create more transparent policies to encourage its growth into future pharmaceutical and medical devices hub.
Rajinder Kumar Suri, Senior Advisor and Former Chief Executive Biologicals, Panacea Biotech</td></tr>
<tr><td>09:20</td><td colspan="2">Addressing pricing, reimbursement and compulsory licensing issues in India
Pricing remains a contentious issues in India. While it is understandable that various government agencies try to reduce drug prices to ensure affordability in India, the lack of reimbursement and potential compulsory licensing of products pose serious operational challenges to pharmaceutical companies. The big question here, is how can we find the middle point between pharma and government, to ensure success for all concerned?</td></tr>
<tr><td>09:40</td><td colspan="2">Keynote panel discussion: Replicating India’s success in Generics to become the global leader in biologics production and research
Whilst India is set on the path to growth, we undoubtedly still face some challenges. To attract more foreign direct investment, we need to overcome fragmented policy and funding shortages, and further improve infrastructure and IPR protection. In this session, a panel of analysts and pharma leaders will address the following topics:
• Where are we now in encouraging innovation in India?
• Repositioning India as a new innovation hub by building a sustainable ecosystem
• Advice to local biotech companies: Strategies to build up a strong base in India without losing out to competition
• Shooting for success: Strategies for replicating India’s success in generics to become the global leader in biologics production and research
Sanjay Singh, CEO, Gennova Biopharmaceuticals</td></tr>
<tr><td>10:20</td><td colspan="2">Networking Refreshment Break</td></tr>
<tr><td></td><td>MARKET ACCESS
ACCESS & REIMBURSEMENT</td><td>MANUFACTURING
UPSCALING</td></tr>
<tr><td>10:50</td><td>Chair’s opening remarks</td><td>Chair’s opening remarks</td></tr>
<tr><td>10:55</td><td>Balancing access, quality and cost: What are the best pricing strategies for antibodies and biosimilars in India?
• Improving accessibility and affordability of prescription drugs by setting a price ceiling
• Understanding how biosimilar pricing policies affect opportunities for domestic and international pharma players
• Investigating methods for reducing operational costs to remain profitable whilst reducing product prices
Hanmant Barkate, Vice President & Head, Medical Affairs, Clinical Development and Regulatory Affairs, Intas Pharmaceuticals</td><td rowspan="2">Panel discussion
Scalable, single use, and continuous systems for improving biomanufacturing productivity in India: What’s possible?
• Understanding the current regulatory challenges in implementing new biomanufacturing processes in Indian manufacturing plants
• Exploring strategies to improve productivity with robust and scalable technology transfer systems
• Investigating cost effective methods to implement single use manufacturing systems in India
• Understanding how continuous systems help to improve productivity and scalability of biologics production
• Developing critical attributes to effectively monitor scalable, single use and continuous manufacturing process
• Performing the right comparability assessments to ensure system robustness
<u>Moderator:</u></td></tr>
<tr><td>11:15</td><td>Navigating India’s regulatory landscape to get your new drugs and biosimilars approved
• Understanding the current challenges in getting new drugs and clinical trials approved in India
• Crafting corrective measurements to improve drugs and trials approved in India</td></tr>
</table>

	• Getting your biosimilars approved in India- A case study	**G S Reddy,** Chief General Manager, Manufacturing, **Indian Immunologicals Limited** **Panellists** - **Vikram Paradkar,** Senior Vice President, Technical Operations, **Biological E** - **Swapnil Ballal,** Senior Director, **Dr Reddy's Laboratories** - **Dakshesh Mehta,** Associate Vice President, Head – Bioprocess Development, Biotech R&D, **Wockhardt**
11:35	**Panel discussion** **Moving beyond traditional reimbursement pathways to make drugs more affordable in India** Less than 1% of the Indian government's GDP is invested yearly in healthcare research and reimbursement. In this panel discussion, regulators and pharma leaders investigate the topics below in an attempt to build a more sustainable healthcare ecosystem in India: • How can the government better support local companies to build a stronger domestic pharmaceutical market? • What is the role of pharma in making drugs more affordable while remaining profitable? • Alternative models for providing affordable drugs without depending on traditional reimbursement models **Amit Varma,** Managing Partner, **Quadria Capital** **Rajesh Naik,** Head Medical Affairs Oncology, **Boehringer Ingelheim**	**Overcoming downstream bottlenecks in the upscaling process** • Investigating how efficient downstream processes help to establish flexible manufacturing systems • Strategies for reducing your downstream footprint whilst speeding up the purification process • Selecting the most innovative tools to overcome downstream bioproduction bottlenecks **Dakshesh Mehta,** Associate Vice President, Head – Bioprocess Development, Biotech R&D, **Wockhardt**
11:55		**Building a hybrid system to create a scalable manufacturing facility** • Balancing costs and benefits by creating a hybrid manufacturing facility in India • Achieving production scale flexibility by integrating traditional manufacturing techniques with semi-perfusion systems • Exploring how single use technology can help in scaling manufacturing production
12:15	**Networking Lunch**	
	BRANDING & COMMUNICATIONS	**QUALITY ASSURANCE**
13:30	**From Bedside to Market- Strategies for transitioning from an investigator to a prescriber** • How is the role of medical affairs personnel evolving, and how can you use it as a tool for building recognition in the market? • Identifying the key stakeholders you need to be interacting with to build credibility • Providing value-added services to patients and other personnel to establish a market leadership position **SD Sinha,** Vice President, Global Pharmacovigilance Clinical Development and Medical Affairs, **Hetero Drugs Ltd**	**Quality risk management (QRM) in implementing new bioprocesses** • Developing the best tools to implement QRM in bioprocessing • From batch to continuous processing, how can pharma manufacturers manage the inherent risks? • Batch vs Semi-batch vs continuous processing: Comparing risk management perspectives **Dhaval Trivedi,** Assistance Vice President, Regulatory Affairs, **Stelis Biopharma (Strides Shasun Entreprise)**

13:50	**Building a "patient-first" communication framework in India** • Understanding what it means to be a truly "patient-first" business • How can you demonstrate "patient-first" as a key element of your brand, whether you are a local or international player? • How can different functions within your business work together to consolidate this approach? **Alap Gandhi,** Head, Medical Affairs, **GSK**	**Establishing proper control strategies for a risk free commercial manufacturing** • Identification of critical quality attributes • Drafting effective control strategies to ensure quality biosimilars production • Working closely with regulators to minimise risk • Continuous process verification **Harish Shandilya,** Head Global Product Development and Regulatory Affairs, **Enzene Biosciences, part of Alkem Laboratories**
14:10	**Developing an effective medical communications strategy for India's biopharma market** • What restrictions are there on marketing strategies for biopharmaceuticals in India? • How can you reach your market? • The bridge between development and commercialisation: What role does medical affairs play in your communications strategy? • Balancing commercial value whilst delivering credible medical information **Praveen Duhan**, Associate Global Medical Director, Global Medical Affairs, **Novartis Healthcare**	**Selecting the right CMO to produce high quality biologics products** • Analysing the most important factors to consider when deciding on a CMO to serve your manufacturing objectives • Differentiating industry reputation and brand recognition from marketing promotional strategies • Cost versus usage rate- are you making the right choice when selecting your CMO?
14:30	**Establishing health economics and outcome research (HEOR) data to your expand international market share** • Strategies for presenting clinical and economic evidence to makers, payers and providers in the international arena • Gaining market access and reimbursement with convincing HEOR data • Delivering essential courses to provide trained workforce to conduct HEOR studies **Rajendra Jani,** Senior Vice President, Clinical R&D, **Zydus Cadila**	**Laboratory Information Management Systems (LIMS) as compliance management tool** • How can modern LIMS keep a company compliant? • Increasing productivity & confidence by reducing transcription and calculation errors • Tools to assure quick response to regulatory audits **Randy Hice,** Manager, Global Strategy**, Abbott Informatics**
14:50	**Networking refreshment break**	
	GOING GLOBAL	**QUALITY CONTROL**
15:20	**Bringing Indian biologics products to global markets – A case study of CPL Biologicals** • From early stage development to the manufacturing phase- how Indian biologics manufacturers can comply with regulatory guidelines and ensure high quality development and production • Overcoming regulatory challenges in exporting Indian products to the global market • Bridging the gap between India and international health product rules and requirements **Nirav Desai,** Vice President, **CPL Biologicals**	**Biosimilars comparability studies and method development in early phase production** • Building target-specific, robust testing kits • Ensuring reproducibility of biologics kits • Optimising assays to ensure successful regulatory submission **Alok Sharma,** Principal Scientist and Head, Analytical Development Lab, Biotech Division, **Lupin Limited**

15:40	**Successfully launching biosimilars in international markets** • Providing essential efficacy data to speed up biosimilars launch in international markets • Justifying pre- and post- launch marketing investment to improve brand awareness • Building international confidence in Indian biosimilar products • How can we replicate India's success as the number one generics supplier to achieve the same status in the global biologics industry? **Chandru Chawla,** Head of Corporate Strategy and New Ventures, **Cipla**	**From development to validation: Analytical method LCM and its associated challenges** • Overview of various method development approaches and highlighting stability indicating assays • Method validation & performance tracking to cope with latest configurations, reagents and alternatives • Exploring automation as a method for streamlining QC processes and maintaining uniformity of analytical processes • Balancing benefits and limitations of automation in data analysis. **Natasha Shanker,** Associate Director, Quality Control **Dr Reddy's Laboratories**
16:00	**Branding strategies for supplying drugs to international market** • Overcoming international concerns around the quality of Indian products • Building relationships with the right people to ensure branding success • Overcoming the challenge of a lack of brand recognition in foreign markets	**Design principles for conducting GMP stability storage and biological stability testing** • Crafting critical quality attributes and stability testing strategies • Deriving control strategies to ensure identity, drug quality, purity and potency • Developing stability protocols for GMP stability testing
16:20	**End of Conference Day 2**	

WHY YOU SHOULD JOIN US AT THE 14th BIOPHARMA INDIA 2016

The move towards a more transparent regulatory regime in India is opening up its biopharma industry once again. With the widely available patient population and low manufacturing cost base, India remains an attractive destination for international biopharma players.

But there are still challenges – quality assurance and control concerns need to be addressed if India wants to supply into the world's most lucrative international markets. R&D also needs to be strongly supported, fostering an environment of innovation and encouraging new biotech start-ups to develop cutting-edge solutions and products. If we can tackle these challenges, India's biopharma opportunity will be extraordinary.

BioPharma India isn't a trade show. We bring senior executives together to explore the most exciting opportunities India's biopharma industry has to offer. With case studies, innovation showcases and interactive panel discussions, you can hear from the movers and shakers and then meet them.

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