2021 3rd Quarterly vetSIG Meeting (April 30th, 2021)

Observer Reports

The meeting was held on Friday, July 30th, 2021. The taster of veterinary medical writing and main item was the talk *One Health, distributed manufacturing and medical writers' expertise* by Jennifer Bell. This was followed by a report on the results of a survey of the veterinary medical writing/communication community, by Henry Smith.

We have two observer reports, one for each of the main topic presented at the meeting, to provide readers with the perspective of an individual audience member for each part.

The slides for Part 1 can be seen on pages 3~5, and those for Part 2 on pages 6~9.

Report Part 1: One Health, distributed manufacturing and medical writers' expertise

Jen's talk was based on her experience as co-author of the paper in *Build a Sustainable Vaccines Industry with Synthetic Biology* in Trends in Biotechnology (the paper can be downloaded here: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7834237/). At the heart of the concept in their paper was the bio-foundry—a small-scale, manufacturing unit that can swing onto vaccine production as soon as it has received the relevant digital code. This would facilitate cheaper vaccine production and substantially shorter supply chains (specifically cold chains), an improvement on the current centralized and capital-intensive model of the vaccines industry, of particular relevance during the current COVID pandemic.

Starting with the link to *One Health*, Jen pointed out a number of ways that bio-foundries could benefit human and animal health. In addition to the many practical and ethical aspects, Jen highlighted one point of great interest to all medical writers. Jen and her co-authors came up with 23 ideas in a brainstorming session; their next job as medical communicators was to convert the raw ideas into section headings and text, a key skill for all of us. From there, the discussion broadened to cover Norwegian salmon—for them, could the age of antibiotics be over? (opinions differed)—and the feasibility of mobile bio-foundries (the barriers may be regulatory rather than physical).

Finally, Jen touched on publication of novel ideas and the future for bio-foundry medical writing. She suggested that authors need to weight up the magnitude of the impact factor and the "goodness of fit" when selecting where to publish a "Eureka" concept. High

impact factors are great of course, but if there is a risk of the article being incorrectly pigeonholed or subject to a reference cap, it may be worth looking at another journal. The writing for this project has so far involved journal articles, but as the concept moves to fruition, we can expect many more opportunities for medical writers, especially in the freelance field. We can be glad Jen and her fellow-authors have found a good audience for their research, and look forward to exciting developments with the advance of bio-foundries.

Henry Smith

Part 2. Survey Report

The purpose of the survey was to characterize EMWA vetSIG participants, and other veterinary medical writers and communicators. The survey included eight questions, the first three of which covered work-related demographics. Respondents had apparently come into diverse areas of veterinary medical communication by diverse routes in most cases, although there were other cases where people hoped to enter the field, and one or two where they had left it. Though specific occupations were not clarified, participants mostly worked in medical/veterinary regulatory, journal article and comms fields. Participants were mainly from Europe (especially, but not exclusively Germany and Austria), and "Specific training" and "Career advice sharing" were the most commonly cited purposes for their participation. The most extensively discussed result was that for the supplementary question on the species the participants focus on. As expected, domestic dogs had the highest ranking, but in out-of-the-blue result, humans also shared the first ranking.

Respondents and participants also shared suggestions and comments for the vetSIG as well. These included the inclusion of topics related such as freelance writing, and activities that could satisfy members with different backgrounds. This point was followed by a comment on presentations in structured meetings to cover those different backgrounds. The discussion also mentioned that the association should include members globally. The meeting closed with reminders of the next events.

Hui-Wen Chen

EUROPEAN MEDICAL WRITERS ASSOCIATION

3rd quarterly Meet&Share in 2021

30 Jul 2021, 3 pm, CET

One Health,
distributed manufacturing and
medical writers' expertise

"Meet&Share" Vet SIG

Free for all in 2021 – only for EMWA members from 2022

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'One Health' is an approach to designing and implementing programmes, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcomes.

- *World Health Organisation*
  https://www.who.int/news-room/q-a-detail/one-health

GMO ethical issues relate to big companies selling expensive technologies that underprivileged communities can't afford

Please read this opinion piece:

Build a Sustainable Vaccines Industry with Synthetic Biology
https://www.cell.com/trends/biotechnology/fulltext/S0167-7799(20)30331-0

'One Health' is an approach to designing and implementing programmes, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcomes.

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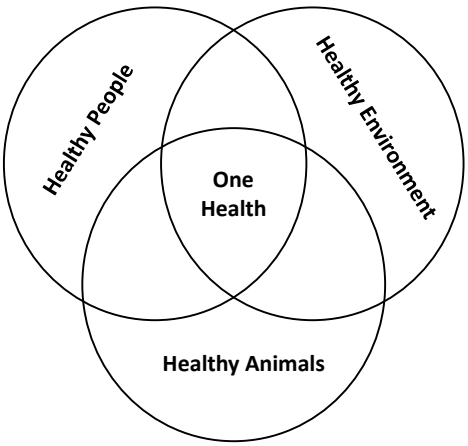

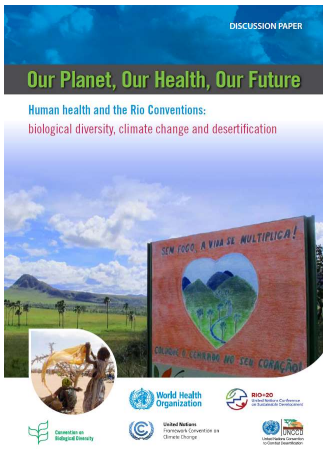

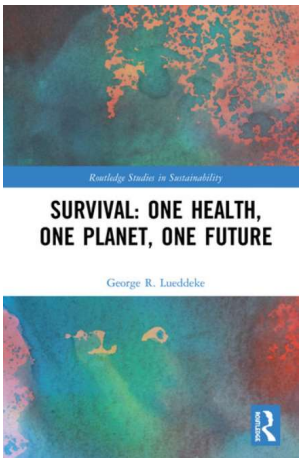

TIBTECH 2032 No. of Pages 9 **ARTICLE IN PRESS**

Trends in Biotechnology

CellPress

Opinion

Build a Sustainable Vaccines Industry with Synthetic Biology

Richard I. Kitney,[1] Jennifer Bell,[2] and Jim Philp[3,*]

The vaccines industry has not changed appreciably in decades regarding technology, and has struggled to remain viable, with large companies withdrawing from production. Meanwhile, there has been no let-up in outbreaks of viral disease, at a time when the biopharmaceuticals industry is discussing downsizing. The distributed manufacturing model aligns well with this, and the advent of synthetic biology promises much in terms of vaccine design. Biofoundries separate design from manufacturing, a hallmark of modern engineering. Once designed in a biofoundry, digital code can be transferred to a small-scale manufacturing facility close to the point of care, rather than physically transferring cold-chain-dependent vaccine. Thus, biofoundries and distributed manufacturing have the potential to open up a new era of biomanufacturing, one based on digital biology and information systems. This seems a better model for tackling future outbreaks and pandemics.

The Vaccine Production Model Needs to Change

The COVID-19 crisis has cast the vaccines industry into scrutiny [1]; an industry that has been silently beleaguered for decades (https://www.who.int/immunization/programmes_systems/procurement/mi/platform/module2/2019_Global_Vaccine_Market_Report.pdf?ua=1). A United States National Academy of Sciences study from 2003 [2] concluded that the amount that the nation spent on vaccines 'appears to be insignificant compared with that spent on other medical and social interventions that may have lesser social benefits.' Large company numbers that supply vaccines have steadily reduced [3]: some 80% of vaccines arise from five multinationals (https://www.who.int/immunization/programmes_systems/procurement/market/global_supply/en/). At the heart of the problem is a tension between relatively poor financial returns to the vaccine industry and the high costs in production and R&D [4].

Compared to small molecule pharmaceuticals, centralised vaccine production facilities are capital intensive [5]. Fixed costs are high [6], especially for new vaccines. For example, the need for eggs for production is at least 70 years old, is expensive and time-consuming, but difficult to replace [7]. In past high-income countries have paid a higher price until the fixed costs are amortised. Then lower-income countries have adopted vaccines as the price has dropped after paying the fixed costs. However, there is now tremendous pressure for a COVID-19 vaccine to be available for all who need it, effectively everyone.

Distributed Manufacturing, a More-Sustainable Vaccine Model

The long distribution chains of centralised vaccine production are patchy, resulting in incomplete geographical coverage [8] (Box 1). Even if there is no overall shortage, there may be where they are needed most. Centralisation of labour and production has been the norm in many industries, but in 2015 the **World Economic Forum** (WEF, see Glossary) put distributed manufacturing in its top ten emerging technologies for the year (https://www.weforum.org/agenda/2015/03/top-

Highlights

Biofoundries incorporate high levels of automation that implement complex workflows in order to increase the reliability and reproducibility of biotechnology.

Biofoundries in different locations can communicate via digital data to complete design/build/test/learn operations.

Distributed manufacturing attempts to bring small-scale manufacturing to many locations, directly in contradiction to the centralised mass production paradigm.

Biofoundries are suited to the design of certain types of vaccines that do not require whole cells.

The design and prototyping of vaccines in biofoundries with final manufacture in small-scale facilities offers the possibility to bring manufacturing close to the point of care.

The marriage of biofoundries and the distributed manufacturing model offers solutions to the troubled vaccines manufacturing industry.

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Things we thought about became article headings:

- Building sustainable industries
- How production models are changing
- Sustainability
- Distributed manufacturing
- Synthetic biology
- Disease outbreak vigilance
- Mobile labs used commonly in Africa
- Other technologies already in use
- Economic viability
- Operations robustness, standardization and quality
- Responsive regulation
- Cybersecurity
- Talent, education and skills
- Competition
- Other sectors where distributed manufacturing works
- Economic growth
- Overcoming challenges with current manufacturing methods
- Local essential medicines production
- Biomedical science
- Disruption
- Dairy farming and genomics
- Aquaculture, antibiotics and vaccines
- Funding

Headings from:
Bell, J., Philp, J. and Kitney, R.I. (2021). Addressing the post-COVID era through engineering biology. *Engineering Biology,* 5, 21-34.

Kitney, R.I., Bell, J. and Philp, J. (2020). Build a sustainable vaccines industry with synthetic biology. *Trends in Biotechnology*. Available in [cited 08 May 2021]: https://doi.org/10.1016/j.tibtech.2020.12.006

DISTRIBUTED MANUFACTURING OF ACCESSIBLE TREATMENTS

As part of the RQA's Coffee Morning discussion series, 14 attendees came together to discuss Distributed Manufacturing on 4th May, 2021.

There has been a lot about RNA vaccines in the news over the last months. Complications have been seen, with delays in vaccine manufacture and distribution. We want to raise awareness of distributed manufacturing and empower under-served communities to help themselves.

The coffee morning started with a presentation based around the ethos of distributed manufacturing, namely that centralised manufacturing commonly practiced by the pharmaceutical industry is challenging as it uses extensive supply chains. These supply chains are risk laden during transport of sensitive medicines in remote locations.

The distributed manufacturing idea overcomes supply chain issues. All required information is electronically transmitted directly to local manufacturing sites. In theory, distributed manufacturing could enable regions to access treatments for themselves. Under-served communities are often thought of as existing in low- and middle-income countries, but they exist in high-income countries too.

The pharmaceutical industry has a wealth of knowledge and experience. It started immense efforts to manufacture and distribute medicine to over eight billion people. This distributed manufacturing idea complements pharmaceutical industry efforts. It is an idea that requires thought and collaboration from lots of people. Constructive, transferrable and innovative ideas are needed as the model has its own challenges.

Pharmaceutical and medical device areas which should be considered include various operations, GxPs and regulations. Some other considerations include angel investors, accreditation, AI, biofoundries, business ecosystems, chemicals, clinics, communication, computing, consumables, crowd funding, culture, digital biology, documents, economics, engineering biology, environment, epidemiology, equipment, ethics, franchises, information technology, law, logistics, machine learning, medicine, mobile labs, mobile manufacturing, monitoring, policy, politics, prediction, records, reagents, regulation, revitalisation, robotics, small scale manufacturing, society, standardisation, supplies, sustainability, synthetic biology, university hospitals, writing...

In time, community manufacturing sites could result in business ecosystems. This would bring more opportunities to those locations. A broader range of biotechnology products could be manufactured.

For example, medicines for a variety of conditions or enhancement of crops for growth under difficult environmental conditions.

More brainstorming and action will make this distributed manufacturing idea a reality. We want to see it establish for the long term. Therefore, the RQA will be setting up a special interest group to work through the aforementioned challenges. We believe that there is a great depth of skills and knowledge that can take this idea forward. If you are interested in joining and participating in this group, please contact [illegible].

(See more about distributed manufacturing in the article on page 28).

Jen Bell, Ekrity Limited

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Jen Bell

BUILD A SUSTAINABLE VACCINES INDUSTRY WITH SYNTHETIC BIOLOGY – A SUMMARY

Jennifer Bell summarises Build a Sustainable Vaccines Industry with Synthetic Biology which is located here: www.cell.com/trends/biotechnology/fulltext/S0167-7799(20)30331-0.

Jen worked in quality management roles in medical device and pharmaceutical manufacturing and clinical trial sectors from 2010 to 2018. She holds a PhD in molecular microbiology and an MSc in pharmaceutical manufacturing technology.

One of her co-authors, Jim Philp, worked in academia, industry and government and has current experience in developing regional science and technology policy. Her other co-author, Richard Kitney, among other accolades, is Professor of Biomedical Systems Engineering at Imperial College London.

R3: RNA, READINESS and RESPONSE

21st July 2021

We need a global network of 'living' biofoundries.
Distributed, multi-product, RNA-based manufacturing capabilities will provide increased access to diverse biologics and sustainable pandemic response.

CEPI (Coalition for Epidemic Preparedness Innovations) and Wellcome Leap are collaborating on establishing a global network of 'living' biofoundries. Distributed, multi-product, RNA-based manufacturing capabilities will provide increased access to diverse biologics and sustainable pandemic response. Wellcome Leap builds bold, unconventional programs, and funds them at scale. Their programs aim to deliver breakthroughs in human health over 5 – 10 years and demonstrate seemingly impossible results on seemingly impossible timelines.

https://wellcomeleap.org/r3

They have a $60M jointly funded program and are soliciting abstracts and proposals for work over three (3) years (with a potential additional one-year option) to either develop the platform, develop products, or demonstrate the platform implementation.

Proposers should clearly relate work in these thrust areas to one or more of the program goals, but are not required to provide both platform technologies and end-to-end demonstrations. Synergies among performers will be facilitated by Wellcome Leap.

Upload your abstract and submit your application before August 13 at 11:59pm ET.

Global Biofoundries Alliance

If you are interested in getting involved with biofoundries, message the Global Biofoundries Alliance (GBA) directly. Here is a link to their contact page: https://biofoundries.org/contact

RNA technology experts are in university molecular biology departments. Look at the GBA members list and consider expanding the alliance to include your chosen university: https://biofoundries.org/members

The Global Biofoundries Alliance is based at Imperial College London. It is a network of institutions that shares knowledge, infrastructure and expertise. The GBA objectives are to:

- "develop, promote, and support non-commercial biofoundries established around the world."
- "intensify collaboration and communication among biofoundries."
- "collectively develop responses to technological, operational, and other types of common challenges."
- "enhance visibility, impact and sustainability of non-commercial biofoundries."
- "explore globally relevant and societally impactful grand challenge collaborative projects."

RQA Members can watch the recent Coffee Morning recording here

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angel investors
machine learning
Pharma and medical device industry operations, GxPs and regulations
prediction
logistics
biofoundries
economics
equipment
accreditation
synthetic biology
AI
small scale manufacturing
supplies
information technology
medicine
business ecosystems
robotics
policy

Medical writing and communication

- **Documents**
- **Records**
- **Standards**
- **Regulations**

sustainability
crowd funding
franchises
monitoring
law
politics
culture
engineering biology
standardisation
ethics
reagents
digital biology
mobile manufacturing
university hospitals
revitalisation
mobile labs
chemicals
computing
environment
epidemiology
consumables
society
clinics

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Item 3: Survey Report

- Main survey (MS) > 7 questions related to veterinary medical communication (VMC)
- 1 supplementary question (SQ) > species
- Aim: Define/Characterize the VMC community, as useful information for planning vetSIG activities

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Survey Participation

- Respondents: 32 (MS); 19 for SQ (species)
- 70/30 split established vs. not established
- 75/25 split DVMs vs. FoVs

Discussion Point

- Good SIG size with potential to grow
- Activities matching a base of 30~40 people (avoid underdeliver and/or overpromise)

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Q1. Which area(s) of VMW do you work in?

ANSWER CHOICES	RESPONSES
Veterinary medicinal product (regulatory, vet ICH)	26.67%
Vet/Animal related research for human drug/device (regulatory, ICH)	10.00%
Public health / One health	10.00%
Communicating with professional audience (articles, presentations, etc.)	46.67%
Communicating with lay audience (stakeholders in vet medicine)	36.67%
Continuing veterinary education	16.67%
Other (please specify)	23.33%

Other

- Not yet / HMW

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Q2. Which statement best describes your professional route into VMW/C?

ANSWER CHOICES	RESPONSES
Veterinary work > VMW	34.38%
Other medical / research work > VMW	15.63%
Writing / Communications specialist > VMW	6.25%
Not in VMW now, but possible future interest in VMW	28.13%
Other (please specify)	15.63%

Other (encapsulation):

- Animal research > VMW > HMW
- DVM > Other medical > Research >VMW

Regulatory
Toxicology

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Q3. Which statement best describes you current working condition?

ANSWER CHOICES	RESPONSES
Full time VMW/ Vet Comms (company employee)	18.75%
Full time VMW/ Vet Comms (freelance, self-employed)	12.50%
Working veterinarian who does some VMW/ Vet Comms	6.25%
Other medical work / researcher who does some VMW/ Vet Comms	12.50%
Medical writer (inc. human medicine) who does some VMW/ Vet Comms	15.63%
Other (please specify)	34.38%

Other:
- HMW, medical journalist (mainly human), human regulatory, editor (VMW rare), quality and regulatory, university teacher

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Qs 1~3. Demographics: Discussion Points

Background, professional odyssey, and current status all suggest:

- No single definition of VWWer / VMCer: Very diverse (+), Hard to please everyone (-)
- Hopefuls, Newbies, Veterans, Vexit-eers
- Journal article, Coms, Regulatory equally all well represented
- More employed than freelance?

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Q4. Please rank the following as a wish list for vetSIG meetings/events

	1	2	3	4	5	TOTAL	SCORE
Discussing my area within VMW	16.67% 5	16.67% 5	20.00% 6	16.67% 5	30.00% 9	30	2.73
Discussing all/other areas of VMW	10.00% 3	20.00% 6	36.67% 11	26.67% 8	6.67% 2	30	3.00
Career opportunities/development in VMW	29.03% 9	19.35% 6	6.45% 2	25.81% 8	19.35% 6	31	3.13
Specific training for VMW tasks	40.00% 12	30.00% 9	10.00% 3	10.00% 3	10.00% 3	30	3.80
Social contact with VMP professionals (vets and friends of vets).	6.45% 2	16.13% 5	29.03% 9	19.35% 6	29.03% 9	31	2.52

Does the raw data seem confusing?

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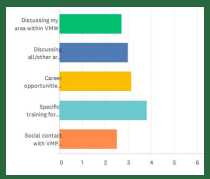
Q4. Please rank the following as a wish list for vetSIG meetings/events



It is confusing (to me)! No central tendency (I think, but best statistical test?)

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Q4. Preference List: Discussion Point

- Training / Career development seem popular (especially for non-established)
- Difficult to fully incorporate into Meet&Share?
- Proactively solicit training/career-related questions for discussion slot
- Webinars, workshops, etc. (future collaborative writing workshops?)
- May not be possible to satisfy everyone every time
- Tie-in with outreach activities?

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Q5. In which country/countries are you and your employer/clients mainly based?

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Q5. In which country/countries are you and your employer/clients mainly based?

Excluding
- Extra-European responses (n=9); Supra-national European responses (n=4)

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Q5. Geographical distribution: Discussion Points

- Global dimension is nice (are we the only global SIG of our kind?)
- Long-term link-ups with American/Australasian MWAs?

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Q6. Can you describe in one or two sentences your future career plan/goals for VMW?

Encapsulation

- Writing for lay audiences and vetICH: common
- Combining VMW with other work: common (with VMC as a smaller part of work)
- Develop regulatory specialization
- Expecting little-to-no VMC work, but interested
- Want to get into VMC field generally
- Continuing veterinary education
- Keep in touch with field after leaving
- Lead writer in a sub-specialized field

- Diversity extends to aspiration

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Q7. Do you have any comments or suggestions for the vetSIG?

Encapsulation (difficult in 1 slide)

- Structured meetings with a speaker
- ~~Recorded~~ / Reported quarterly SIG meetings?

- Forum
- More regulatory (and VMW regs <>HMW regs)

- Career advice

- Thank you to positive messages as responses to this question

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SQ: What species feature in your medical writing?

- Most exciting part of the survey!
- Trying to find out are VMCers as specialized as DVMs (e.g. small animal surgery, large animal, etc.)
- Aimed for species that have recently featured (not every animal ever written about)
- Let's look at results

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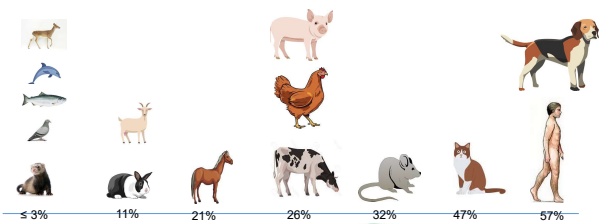
What species feature in your medical writing?



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Featured Species: Discussion Point
VMCers are diverse in what we write about
Could this be a career plus (for vets that want to range widely?)
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