Delphi Study - Additive Manufacturing in the context of medical devices: Round 1

Delphi Study on Challenges and Opportunities concerning the use of Additive Manufacturing in the context of medical devices production and supply chain
The survey will take about 15 minutes to complete. Each page is made of one or two questions.

* Mandatory

Research and Round Description

This study is focused on the use of Additive Manufacturing (also known as 3D printing) in medical supply chains. Additive Manufacturing (AM) is a production method where parts are produced layer-by-layer starting from a CAD file.

Due to the ***opportunities*** that it provides, AM has been used in medical supply chains to produce many different medical parts. However, the use of AM in medical supply chains is still behind its potential due to a series of ***challenges*** that limit its adoption.

The goal of the research is to identify the challenges and opportunities connected with the use of AM in medical supply chains. The identified challenges will help to tune future research, aiming to mitigate or eliminate such challenges, whereas the identified opportunities will help to improve the adoption of AM in medical supply chains.

This round requires to evaluate the relevance of proposed **Challenges and Opportunities** concerning the use of Additive Manufacturing (AM) in the context of medical devices on a scale from ***1 – not relevant*** to ***5 – extremely relevant***. Challenges and Opportunities are proposed as affirmative sentences about which the participant should express his/her opinion. **The evaluations of single participants will not be shared with others**, in order to assure anonymity.

Anagraphical Informations

1. Name:

2. Surname:

Evaluation of Challenges

Challenge 1

3. Evaluate the relevance of the challenge **"Supplier Dependency"** as described below:

   "Only few suppliers are able to procure suitable AM raw materials and/or parts, causing a lack of alternative suppliers"

   (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
   *

1	2	3	4	5

Not relevant Very relevant

4. With reference to the previous challenge (**"Supplier Dependency"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Challenges

Challenge 2

5. Evaluate the relevance of the challenge **"High Production Costs"** as described below:

   "Producing medical devices in AM has production costs which are much higher than those of conventional manufacturing techniques"

   (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
   *

1	2	3	4	5

Not relevant Very relevant

6. With reference to the previous challenge (**"High Production Costs"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Challenges

Challenge 3

7. Evaluate the relevance of the challenge **"High Investment Costs"** as described below:

   "The investment costs necessary to purchase AM machines are very high"

   (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
   *

1	2	3	4	5
Not relevant				Very relevant

8. With reference to the previous challenge (**"High Investment Costs"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Challenges

Challenge 4

9. Evaluate the relevance of the challenge **"High Material Costs"** as described below:

   "The costs of AM raw materials are very high"

   (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
   *

1	2	3	4	5

Not relevant Very relevant

10. With reference to the previous challenge (**"High Material Costs"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Challenges

Challenge 5

11. Evaluate the relevance of the challenge **"IP Issues"** as described below:

    "The use of AM for producing medical devices is accompanied by issues related to Intellectual Properties infringements and data breaches"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5

    Not relevant Very relevant

12. With reference to the previous challenge (**"IP Issues"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Challenges

Challenge 6

13. Evaluate the relevance of the challenge **"Social Sustainability"** as described below:

    "AM requires less workforce than conventional manufacturing techniques (an operator can operate more than one AM machine) and hence employees are reluctant to its adoption"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
    *

1	2	3	4	5

Not relevant Very relevant

14. With reference to the previous challenge (**"Social Sustainability"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Challenges

Challenge 7

15. Evaluate the relevance of the challenge **"Standardization and Certification"** as described below:

    "Being AM a quite new manufacturing technology, there is a lack of standards and certification processes which complicate its use for medical devices"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5
Not relevant				Very relevant

16. With reference to the previous challenge (**"Standardization and Certification"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Challenges

Challenge 8

17. Evaluate the relevance of the challenge **"Material Limitation"** as described below:

    "Not all materials are producible via AM due to the lack of either suitable raw materials or suitable AM technologies (or both)"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
    *

1	2	3	4	5

    Not relevant Very relevant

18. With reference to the previous challenge (**"Material Limitation"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Challenges

Challenge 9

19. Evaluate the relevance of the challenge **"Specialized Workforce (Design Phase)"** as described below:

    "AM requires specialized workforce during the design phase to exploit design benefits such as those achievable through topology optimization procedures"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5
Not relevant				Very relevant

20. With reference to the previous challenge (**"Specialized Workforce (Design Phase)"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Challenges

Challenge 10

21. Evaluate the relevance of the challenge **"Specialized Workforce (Production Phase)"** as described below:

    "AM requires specialized workforce to operate AM machines with proper knowledge on key decisions such as production parameters to be adopted, post process operations, ..."

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5

Not relevant Very relevant

22. With reference to the previous challenge (**"Specialized Workforce (Production Phase)"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Challenges

Challenge 11

23. Evaluate the relevance of the challenge **"Production Limitation"** as described below:

    "Production speed and size are limited and lower than conventional manufacturing techniques"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5

    Not relevant Very relevant

24. With reference to the previous challenge (**"Production Limitation"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Challenges

Challenge 12

25. Evaluate the relevance of the challenge **"Need for post-process operations"** as described below:

    "AM parts cannot be used as-is after production, but they need to undergo to post-process operations (heat treatments, polishing, ...)"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5
Not relevant				Very relevant

26. With reference to the previous challenge (**"Need for post-process operations"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Challenges

Challenge 13

27. Evaluate the relevance of the challenge **"Quality"** as described below:

    "AM medical parts are characterized by mechanical properties that are either low or uncertain (or both)"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5

    Not relevant — Very relevant

28. With reference to the previous challenge (**"Quality"**), please indicate potential countermeasures (OPTIONAL)

Evaluation of Opportunities

Opportunity 1

29. Evaluate the relevance of the opportunity **"Hedged Sourcing Strategy (Demand Risks)"** as described below:

    "Integrating conventional manufacturing and additive manufacturing can minimize demand-related supply chain risks"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5
Not relevant				Very relevant

Evaluation of Opportunities

Opportunity 2

30. Evaluate the relevance of the opportunity **"Hedged Sourcing Strategy (Supply Risks)"** as described below:

    "Integrating conventional manufacturing and additive manufacturing can minimize supply-related supply chain risks"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5
Not relevant				Very relevant

Evaluation of Opportunities

Opportunity 3

31. Evaluate the relevance of the opportunity **"Resilient Supply Chain"** as described below:

"Adopting AM can reduce and/or mitigate the impact of supply chain disruptions since it allows to bring the production closer to the point of use"

(1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
*

1	2	3	4	5

Not relevant Very relevant

Evaluation of Opportunities

Opportunity 4

32. Evaluate the relevance of the opportunity **"Environmental Sustainability"** as described below:

    "The possibility provided by AM to produce parts close to the point of use reduces the environmental footprint of the supply chain since shorter transportation routes are required"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5

Not relevant Very relevant

Evaluation of Opportunities

Opportunity 5

33. Evaluate the relevance of the opportunity **"Reduced Need of Employees"** as described below:

    "AM requires less workforce than conventional manufacturing techniques (an operator can operate more than one AM machine)"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5
Not relevant				Very relevant

Evaluation of Opportunities

Opportunity 6

34. Evaluate the relevance of the opportunity **"Customization"** as described below:

"AM enables a higher degree of customization than conventional manufacturing techniques, derived mainly from a higher design freedom (e.g. topology optimization procedures)"

(1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
*

1	2	3	4	5

Not relevant Very relevant

Evaluation of Opportunities

Opportunity 7

35. Evaluate the relevance of the opportunity **"Responsiveness (On-Demand Production)"** as described below:

    "AM assures quick responses to new orders due to the on-demand production"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5
Not relevant				Very relevant

Evaluation of Opportunities

Opportunity 8

36. Evaluate the relevance of the opportunity **"Responsiveness (Geographical Convenience)"** as described below:

    "AM assures quick responses to new orders due to the production close to the point of use"

    (1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
    *

1	2	3	4	5
Not relevant				Very relevant

Evaluation of Opportunities

Opportunity 9

37. Evaluate the relevance of the opportunity **"Waste Reduction"** as described below:

"AM assures a buy-to-fly ratio of almost 1:1, thus drastically reducing waste compared to conventional manufacturing techniques
(Buy-to-fly is the ratio of the mass of the starting raw material to the mass of the final product)"

(1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
*

1	2	3	4	5

Not relevant Very relevant

Evaluation of Opportunities

Opportunity 10

38. Evaluate the relevance of the opportunity **"MTO Production"** as described below:

"AM enables the possibility to switch from make to stock (MTS) to make to order (MTO) and hence to lower inventory levels (and hence costs)"

(1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
*

1	2	3	4	5

Not relevant Very relevant

Evaluation of Opportunities

Opportunity 11

39. Evaluate the relevance of the opportunity **"Simpler Supply Chain"** as described below:

"AM simplify the supply chain since it encompasses less actors in the supply chain"

(1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
*

1	2	3	4	5
Not relevant				Very relevant

Evaluation of Opportunities

Opportunity 12

40. Evaluate the relevance of the opportunity **"Part Consolidation"** as described below:

"AM enables to consolidate existing part assemblies made from many components into a single part"

(1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant) *

1	2	3	4	5

Not relevant Very relevant

Evaluation of Opportunities

Opportunity 13

41. Evaluate the relevance of the opportunity **"Shareability"** as described below:

"AM allows to easily share products design as they only need to be shared via CAD files to be ready to be printed"

(1 – not relevant; 2 – slightly relevant; 3 – moderately relevant; 4 – relevant; 5 – very relevant)
*

1	2	3	4	5

Not relevant Very relevant
